UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MOLINA HEALTHCARE, INC., Plaintiff, v. CELGENE CORPORATION AND BRISTOL-MYERS SQUIBB COMPANY, Defendants.	Civil Action No. _____ **COMPLAINT** JURY TRIAL DEMANDED

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Plaintiff Molina Healthcare, Inc. ("Plaintiff" or "Molina") hereby sues Defendant Celgene Corporation ("Celgene") and Defendant Bristol-Myers Squibb Company ("Bristol-Myers Squibb"). Based on personal knowledge as to facts pertaining to it, and upon information and belief as to all other matters, Plaintiff alleges as follows:

I. NATURE OF THE CASE

1. This case arises from Defendants' anticompetitive scheme to monopolize the markets for Thalomid and Revlimid by successfully interfering with competitors' efforts to develop and/or obtain U.S. Food and Drug Administration ("FDA") approval for generic versions of Revlimid and/or Thalomid at each progressive step of development, before paying rivals to delay market entry and allocate markets. As part of this anticompetitive scheme, Plaintiff alleges that Celgene:

(1) manipulated the safety program designed to protect patients from thalidomide's and lenalidomide's teratogenic properties to refuse samples to would-be generic competitors;

(2) prevented ingredient suppliers from supplying active pharmaceutical ingredient ("API") to would-be generic competitors;

(3) fraudulently obtained various patents from the U.S. Patent and Trademark Office ("USPTO") for Revlimid and Thalomid and their associated safety distribution protocols;

(4) filed baseless citizen petitions with FDA to stymie generic approvals;

(5) serially commenced "sham" patent infringement lawsuits; and

(6) resolved those lawsuits by entering into anticompetitive reverse payment agreements that delayed the entry of lenalidomide, allocated the lenalidomide market among itself

and its generic competitors, and delayed robust generic competition for at least four-and-a-half years, until January 21, 2026.[1]

2. When Celgene's efforts failed to prevent (but which still *substantially delayed*) a would-be competitor from prosecuting an Abbreviated New Drug Application ("ANDA"), and FDA approval of an ANDA for a generic version of Revlimid or Thalomid became possible, Celgene *further delayed* generic competition by executing an anticompetitive reverse payment settlement agreement with Natco, the first-filer on Revlimid, whose terms were shored up by settling with several later-filing generic companies.[2]

3. The unlawful "reverse payment" to Natco, and its marketing partner Teva,[3] comprised a two-pronged in-kind payment: (1) a volume limited, royalty-free generic license before full generic competition began, amounting to hundreds of millions of dollars in payment to Natco; and (2) acceleration or most-favored entry clauses ("MFE clauses") that both deterred later-filing generics from challenging Celgene's patents through judgment and induced Natco to accept a later entry date by eliminating the risk that Natco loses its lucrative exclusivity period. These MFE clauses, furthermore, laid the foundation for a series of market allocations with the later-filing generics. Celgene settled these later suits on terms that served to shore up the anticompetitive terms (and the attendant windfall of profits) of the reverse payment Natco agreement settlement.

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[1] This action is an opt-out direct action of a class case in which this Court sustained allegations regarding the exact same overall monopolistic scheme here detailed. *See* Opinion, *In re Thalomid and Revlimid Antitrust Litigation*, 2:14-cv-06997, ECF No. 68 (D.N.J. Oct. 29, 2015).

[2] Copies of the later settlement agreements, or fulsome descriptions of their terms, are not publicly available.

[3] For clarity, this Complaint refers to Natco and the partnering companies that developed and now market the related Revlimid ANDA product collectively as "Natco." Natco originally partnered with Watson Pharmaceuticals, Inc., and then with Arrow. Following a series of corporate acquisitions, Teva is the current successor to, or beneficiary from, the settlement agreement between Celgene, Natco, Arrow, and Watson, and markets the ANDA product under the Teva brand name.

4. In 1998, Celgene obtained FDA approval to market Thalomid® (thalidomide) for a leprosy complication known as erythema nodosum leprosum ("ENL"). In 2005, Celgene successfully developed a thalidomide analog, Revlimid® (lenalidomide), and obtained FDA approval to market it for a specific chromosomal variant of myelodysplastic syndromes ("MDS"). Celgene would go on to obtain FDA approvals for additional Revlimid indications, including for a subset of multiple myeloma ("MM") patients in 2006,[4] and later for a subset of mantle cell lymphoma ("MCL") patients in 2013.

5. However, thalidomide, the chemical composition essential to Thalomid and Revlimid, itself dates back to the 1950s and 1960s, when it was banned for decades due to its role in causing severe birth defects.[5] Despite its invention decades before, Celgene has successfully conspired to insulate Revlimid and Thalomid from competition, allowing it to charge supracompetitive prices since 2006.[6]

6. In fact, Celgene has routinely increased its price either once or twice per year. A recent congressional report examining Celgene's pricing practices observed that "[s]ince launching Revlimid in 2005, Celgene raised the price of the drug 22 times, from $215 per pill to $719 per pill. After Bristol-Myers Squibb obtained the rights to Revlimid [in] November [2019],

[4] Under FDA's orphan drug exclusivity program, 21 U.S.C. §§ 360aa-cc, FDA may not approve a generic equivalent for a specific indication or "rare disease" that a brand drug is FDA-approved to treat for a period of seven (7) years. MM is such a "rare disease." Therefore, until May 25, 2013, FDA could not approve a generic thalidomide for the treatment of MM. It could, nevertheless, approve generic thalidomide for the treatment of other indications. This is known as a "skinny label," which allows for market entry prior to the expiration of all exclusivities related to a drug.

[5] Amanda Schaffer, *Thalidomide's Comeback*, SLATE, Jan. 10, 2011, http://www.slate.com/articles/double_x/doublex/2011/01/thalidomides_comeback.html.

[6] *See* U.S. House Committee on Oversight and Reform, Staff Report, *Drug Pricing Investigation*: *Celgene and Bristol-Myers Squibb—Revlimid* (Sept. 30, 2020), at p. 17, *available at* https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf (accessed Apr. 8, 2020) ("Oversight Committee Revlimid Report") ("Celgene uses a series of anticompetitive tactics to suppress generic competition and maintain its high price of Revlimid.")

it raised the price of Revlimid again, to $763 per pill."[7] As Celgene's former Senior Vice President of Sales and Marketing testified, Celgene's tactics allowed it to raise prices "at any time."[8]

7. In 2006, a month's supply of Revlimid cost $6,195.[9] In 2010, the price was about $8,000 for a one-month supply. When Thalomid first entered the market, it cost approximately $6 per capsule. In 2014, its price soared to as much as $357 per capsule, and today, a twenty-eight-day supply of Thalomid costs patients and their health insurers as much as $24,000.

8. In spite of these price increases, Celgene never saw a decrease in quantity demanded for the two branded drugs because Celgene illegally blocked and continues to block generic competition.

9. Celgene's monopolistic efforts with respect to Revlimid have been enormously profitable. Since 2014 alone, Celgene has sold over $40 billion worth of Revlimid in the U.S.:

[7] *Id.*, at p. i.

[8] *Id.*, at p. 4.

[9] Katherine Streeter, *How A Drugmaker Gamed The System to Keep Generic Competition Away* (May 17, 2018), https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

Revlimid

Year	Approximate U.S. Sales
2014	$ 2.9 billion
2015	$ 3.5 billion
2016	$ 4.4 billion
2017	$ 5.4 billion
2018	$ 6.5 billion
2019	$ 7.2 billion
2020	$ 8.3 billion
2021	$ 8.7 billion

10. After Celgene executed an anticompetitive reverse payment agreement with first filer Natco in January 2016, Celgene's consistent and egregious price hikes exploded Revlimid's monopoly profits. U.S. revenue skyrocketed from $3.5 billion[10] in 2016 to $8.7 billion in 2021 – the last year before (delayed) generic entry.[11] Revlimid is now the second-highest grossing drug worldwide,[12] and is projected to reach nearly $14 billion in worldwide sales by 2022.[13]

11. Celgene's anticompetitive tactics to block and delay generic entry have caused Plaintiff to pay supracompetitive prices for these drugs in violation of federal antitrust laws, and

[10] Celgene Corporation Annual Report, 2016 https://s24.q4cdn.com/483522778/files/doc_news/archive/CELG_News_2017_1_26_General_Releases.pdf.

[11] Bristol Myers Squib Annual Report, 2021 https://annual-report.bms.com/assets/bms-ar/documents/2021-annual-report.pdf.

[12] Amy Brown, *EP Vantage 2017 Preview* (Dec. 2016), http://info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.

[13] Evaluate Ltd., *EvaluatePharma Orphan Drug Report 2017* (Feb. 2017), http://info.evaluategroup.com/rs/607-YGS-364/images/EPOD17.pdf. Not surprisingly, Revlimid was the top-selling "orphan drug" in the United States in 2016. *Id.* "An orphan drug is a pharmaceutical product aimed at rare diseases or disorders." *Id.*

states' antitrust, consumer protection, and trade practices laws. Plaintiff seeks civil damages it has incurred and injunctive relief.

II. JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1332 and 1337. The Court has jurisdiction over Plaintiffs' claim for injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

13. This Court has personal jurisdiction over Defendants because Defendants are present in the United States, do business in the United States, have registered agents in the United States, may be found in the United States, and are otherwise subject to the service of process provisions of 15 U.S.C. § 22.

14. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, 28 U.S.C. §§ 1391(b) and (c). Defendants transact business within this district, have agents and can be found in this district, and the relevant interstate trade and commerce is carried out, in substantial part, in this district.

III. PARTIES

15. Molina Healthcare, Inc. ("Molina") is a publicly traded healthcare management organization headquartered in Long Beach, California and incorporated under the laws of Delaware. Molina, through local licensed subsidiaries, provides managed healthcare services under the Medicaid, Medicare and other government-sponsored healthcare programs for low-income families and individuals, including Marketplace members. Through its subsidiaries, Molina services approximately 4.6 million members.

16. The benefits for Molina health plans include prescription drug coverage under which claims for Thalomid and Revlimid have been, and continue to be, submitted and paid.

17. Molina Healthcare, Inc. is the parent company, and assignee of the claims asserted in this action, of subsidiaries and affiliates that provide health insurance that cover medical expenses incurred by the plan beneficiaries. These assignor subsidiaries include: Molina Healthcare of California, Molina Healthcare of Florida, Inc., Molina Healthcare of Illinois, Inc., Molina Healthcare of Kentucky, Inc., Molina Healthcare of Michigan, Inc., Molina Healthcare of Mississippi, Inc., Molina Healthcare of Missouri, Inc., Molina Healthcare of New Mexico, Inc., Molina Healthcare of New York, Inc., Molina Healthcare of Ohio, Inc., Molina Healthcare of Puerto Rico, Inc., Molina Healthcare of South Carolina, Inc., Molina Healthcare of Texas, Inc., Molina Healthcare of Utah, Inc. (d/b/a Molina Healthcare of Utah and Molina Healthcare of Idaho), Molina Healthcare of Virginia, Inc., Molina Healthcare of Washington, Inc., and Molina Healthcare of Wisconsin, Inc. (collectively, the "Molina Subsidiaries").[14]

18. The Molina Subsidiaries reimbursed their members' Thalomid and Revlimid purchases in Alabama, Arizona, California, Colorado, Florida, Georgia, Illinois, Kansas, Michigan, Missouri, Mississippi, North Carolina, New Jersey, New Mexico, New York, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Washington, and Wisconsin.

19. The benefits for Molina plans include prescription drug coverage under which claims for Thalomid and Revlimid have been, and continue to be, submitted and paid.

20. Defendant Celgene Corporation is a drug manufacturer, incorporated in Delaware and headquartered at 86 Morris Avenue, Summit, New Jersey. Celgene manufactures and markets Thalomid and Revlimid.

[14] Molina Healthcare of New York, Inc. is a New York corporation with its principal executive offices located in North Syracuse, New York.

21. Defendant Bristol-Myers Squibb Company is a biopharmaceutical drug company incorporated under the laws of Delaware with its principal executive offices located at 430 E. 29th Street, 14 FL, New York, NY 10016. Bristol-Myers Squibb is a publicly-traded corporation registered on the New York Stock Exchange under the symbol "BMY."

22. Bristol-Myers Squibb Company wholly owns Celgene Corporation as its subsidiary. Bristol-Myers Squibb completed the acquisition of Celgene in November 2019 after the companies had executed a merger agreement in January 2019. "The companies' public statements and filings with the Securities and Exchange Commission make clear that Revlimid, which had nearly $10 billion in annual revenue, was a key asset in the transaction. [¶] The companies' joint SEC filings for the merger acknowledge that Revlimid revenue was so critical that any expiration of its patent protection sooner than anticipated 'would be harmful to the combined company and could have a material adverse effect on its business, financial condition or results of operations.'"[15] In the first full year after the acquisition (2020), Bristol-Myers Squibb reported more than $12.1 billion in Revlimid revenue.[16]

IV. ECONOMIC BACKGROUND

23. For most consumer products, the person responsible for paying for them is also the person selecting them. The pharmaceutical marketplace departs from this norm.

24. Prescription drugs may only be dispensed pursuant to a doctor's prescription, and a licensed pharmacist may dispense only the brand-name drug named in the prescription or its AB-rated,[17] FDA-approved generic equivalent.[18]

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[15] Oversight Committee Revlimid Report, at p. 2 (footnote omitted).

[16] Bristol-Myers Squibb Company, *Form 10-K 2020*, at p. 46, available at https://www.sec.gov/ix?doc=/Archives/edgar/data/14272/000001427221000066/bmy-20201231.htm#i41f64878d2784d5ea6ffaae4477d4823_97.

[17] FDA grants an AB-rating to generic drugs that meet necessary bioequivalence requirements.

[18] In many states, pharmacists must substitute an AB-rated generic for a brand-name drug without seeking permission from the prescribing doctor.

25. In most instances, the patient and his or her health insurer pay for the prescription drug that a doctor has prescribed. Therefore, the doctor's prescription defines the relevant product market because it limits the patients' (and pharmacist's) choice to the drug named therein.

26. When there is no generic competition for a brand-name drug, the brand manufacturer can set and maintain prices without losing sales. The ability to do this is the result of the brand name drug company's monopoly power over the market for that drug in both its brand-name and generic form. When an AB-rated generic is available, price competition is introduced. Formulary design and state generic substitution laws give purchasers a chance to substitute on the basis of price, and they do, as price is the only material difference between a brand and AB-rated generic version.

27. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a brand-name drug predictably decrease, sometimes as much as by 90%, because of price competition among generic manufacturers.[19] FDA reports that one year after entry, a generic drug takes over 90% of the corresponding brand-name drug's sales at 15% of the price. Generic drug entry, therefore, is a huge threat to the continued profitability of a branded drug. Much lower brand drug profits translate to benefits to purchasers.

28. According to the IQVIA Institute—the leading provider of data in the healthcare sector—since 2013, for drugs where a generic is available, consumers purchase the generic 97%

[19] See, e.g., Jon Leibowitz, "Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (June 23, 2009), http://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements-pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf.

of the time.[20] The Federal Trade Commission ("FTC") has found that on average, within a year of generic entry, prices had dropped 85%.[21] As a result, competition from generics is viewed by brand manufacturers as a serious threat to their bottom line.

29. In sum, generic competition enables purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price.

30. For every rung in the prescription drug ladder, except for the brand-name drug manufacturer, there is a financial benefit to choosing the generic drug. Pharmacies normally earn a higher markup on generic drugs because of pricing structure and federal reimbursement rules and private health insurers typically offer incentives to pharmacies and members to fill prescriptions with generics such as lower copays for generic drugs than for brand-name drugs.

31. Generic competition enables third party payers like Plaintiff to purchase a generic version of a brand-name drug at substantially lower prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no generic drug which competes effectively with the brand-name drug, and therefore, the brand-name manufacturer can charge supracompetitive prices without losing sales. Given their acute knowledge of the effects of generic entry into a market, brand-name manufacturers like Celgene have a strong incentive to delay such entry through various means, including by serially filing frivolous patent infringement lawsuits and entering illegal "pay for delay" settlement agreements.

V. BACKGROUND

[20] IQVIA Institute, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022* at 14 (2018), *available at* https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

[21] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study").

A. The Regulatory Structure for Brand and Generic Drugs

1. The Hatch-Waxman Act and NDA Approval Process

32. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), a manufacturer that creates a new, pioneer drug must obtain FDA approval to sell the drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug and identify any patents claiming the drug. 21 U.S.C. § 355(b).

33. When FDA approves a brand-name manufacturer's NDA, it lists in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents which, according to the information supplied to FDA by the brand-name manufacturer: (1) claim the approved drug or its approved uses; and (2) for which a "claim of patent infringement could reasonably be asserted if a person is not licensed by the owner engaged in the manufacture, use, or sale of the drug."[22]

34. FDA does not investigate the patents or verify the NDA sponsor's representations for accuracy or trustworthiness prior to listing patents in the Orange Book. Listing such a patent is a purely ministerial act.

35. Once a brand manufacturer lists a patent in the Orange Book, it creates the possibility for the brand company to later sue a generic competitor for infringing the listed patent before the competitor has launched its product and, in doing so, trigger an automatic 30-month stay of FDA approval. The 30-month stay is the benefit to the brand. The benefit to the generic is having some information about which patents the brand company believes claims the drug and could reasonably be asserted in litigation (per the two-part statutory test above).

[22] 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(g)(7)(A)(iii).

36. Not all patents that may claim or cover aspects of a drug product or its manufacture may be listed in the Orange Book; for example, patents that claim a process of making a drug, product packaging, aspects of a device used to deliver a pharmaceutical composition, and REMS programs do not meet the statutory and regulatory standard and cannot be properly submitted for listing in the FDA's Orange Book.

37. The Orange Book is not the only means for generics to understand the relevant patent coverage for the brand products. Generic companies routinely dedicate significant resources to surveying the patent landscape (including hiring consultants) to understand what other unlisted patents exist that may, arguably, cover the brand drug. Having done the work to understand the brand's patent coverage, generic companies then routinely develop their product by designing around the brand's existing patent coverage (even going so far as to design around patents that the generic has reason to believe are invalid and/or unenforceable).

2. The Hatch-Waxman Act and ANDA Approval Process

38. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman Act ("Hatch-Waxman"). Congress' principal intent was for Hatch-Waxman to simplify and reduce the regulatory hurdles for prospective generic manufacturers, by replacing the lengthy and costly NDA approval process with an expedited ANDA review process.[23] Under Hatch-Waxman, an ANDA applicant may rely on the safety and efficacy findings of the NDA for the referenced brand-name drug if the ANDA demonstrates the proposed generic drug is therapeutically equivalent and "bioequivalent," ("BE") *i.e.*, it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug, and is

[23] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

absorbed at the same rate, and to the same extent, as the brand-name drug. For ANDAs that pass this test, FDA assigns an "AB" rating to the generic drug.

39. BE is generally demonstrated via studies in which the proposed generic is compared to the Reference Listed Drug ("RLD," which is, in this instance, the brand-name drug) in either *in vivo* or *in vitro* studies.[24] These studies require the ANDA applicant to have access to sufficient samples of the RLD to conduct the necessary comparisons. Without RLD samples, it is impossible to complete and file an ANDA application.

40. FDA illuminates the issue:

> To obtain approval for a generic drug, the generic company needs to show, among other things, that its version of the product is bioequivalent to the RLD [i.e. the brand drug, or reference listed drug]. This usually requires the generic company to conduct bioequivalence studies comparing its product to the RLD, and to retain samples of the RLD used in testing after a study is complete. To conduct these kinds of bioequivalence studies, the generic company needs to obtain samples (generally between 1,500 and 5,000 units) of the RLD.[25]

41. Only samples of the RLD approved by FDA and marketed in the United States may be used for BE testing purposes. In the ordinary course, a prospective ANDA sponsor obtains samples by buying them, at market price, from a drug wholesaler or distributor. Wholesalers and distributors are large companies that buy drugs from manufacturers for the purpose of re-selling them to pharmacies or other entities. Generic companies are authorized to buy prescription drugs from distributors for BE testing purposes.

42. Celgene's own former senior vice president of global regulatory affairs, drug safety, risk management, and quality assurance Graham Burton testified that Celgene is the only

[24] *In vivo* studies are studies conducted on live subjects. *In vitro* studies are conducted in a laboratory.

[25] FDA, *Reference Listed Drug (RLD) Access Inquiries*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Feb. 26, 2019).

source from which a generic company could obtain Revlimid or Thalomid for purposes of BE testing.[26]

3. The Hatch-Waxman's Balancing Act

43. As a counterbalance to Hatch-Waxman's simplified ANDA process, Hatch-Waxman also provides brand manufacturers with the ability—merely by filing a patent infringement lawsuit—to easily obtain what is essentially a preliminary injunction, in the form of an automatic stay of up to thirty months, of FDA's ability to approve a generic manufacturer's ANDA.

44. To obtain FDA approval of an ANDA, the generic manufacturer must certify that it will infringe no patent listed in the Orange Book claiming the brand drug, because either:

a. No patent for the brand-name drug has been filed with FDA (a "Paragraph I Certification");

b. The patent for the brand-name drug has expired (a "Paragraph II Certification");

c. The patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

d. The patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV Certification").[27]

45. When a generic manufacturer files a Paragraph IV Certification, it must notify the brand manufacturer and patent owner. The ANDA filing itself becomes an artificial act of patent infringement, entitling the patent holder to sue for injunctive relief, according to Hatch-Waxman.

46. If the patent holder sues the ANDA filer within forty-five days of receiving the Paragraph IV Certification, Hatch-Waxman prevents FDA from granting final approval to the

[26] Exhibit to Brief in Opposition to Motion for Summary Judgment, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02095-ES-MAH (D.N.J. Mar. 20, 2018) ("MSJ Opp."), Dkt. No. 285-15 at 69-70.

[27] 21 U.S.C. § 355(g)(2)(A)(vii).

ANDA until the earlier of (a) thirty months after the lawsuit is commenced, or (b) the court presiding over the patent infringement action rules that the patent is invalid or not infringed by the ANDA.[28] It is almost always the case that the 30-month period expires before the court rules, resulting in a 30-month statutory stay.

47. However, during the 30-month stay, FDA may grant "tentative approval" to an ANDA applicant if the agency determines that the ANDA would qualify for final approval, but for the 30-month stay.

4. The first filer's 180-day exclusivity period.

48. Generics may be classified as (i) first-filer generics, (ii) later generic filers, or (iii) authorized generics.

49. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first Paragraph IV generic manufacturer ANDA filer ("first-filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. That is, when a first filer submits a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first-filing generic has been on the market for 180 days.

50. The 180-day window is often referred to as the first-filer's six-month or 180-day "exclusivity"; this is a bit of a misnomer because a brand manufacturer (such as Celgene) can launch an authorized generic ("AG") at any time, even prior to first-filer generic entry. An AG is an approved brand name drug, like Revlimid, that although marketed without the brand name on

[28] 21 U.S.C. § 355(j)(5)(B)(iii).

its label, is the exact same drug product as the branded product. Through an AG, brand manufacturers can enjoy the competitive benefits of marketing both their branded and a "generic" drug, capturing sales from customers interested in either.[29] Thus, brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales (from the branded product to a generic/AG product) they would otherwise lose entirely to the generic entrant.

51. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first-filer.

52. A first-filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing forms of generics.

5. Patents are subject to judicial and administrative scrutiny.

53. A patent may be valid or invalid, infringed or not infringed, and enforceable or unenforceable. Simply owning a patent does not entitle the patent owner to exclude others. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the Patent and Trademark Office ("PTO"), by court decision, or by jury verdict.

54. A patent holder at all times bears the burden of proving infringement. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

[29] An AG thus does not need to go through the Abbreviated New Drug Application ("ANDA") process because it is the exact same drug product as the branded product.

55. A patent is invalid or unenforceable when: (i) the disclosed invention is obvious in light of earlier prior art; (ii) when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material or submits materially false information to the PTO during prosecution; and/or (iii) when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

56. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

57. In practice, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.

6. FDA Can Impose REMS

58. Since at least the 1960s, FDA has examined and implemented various methods for managing risks related to pharmaceutical products. Methods have included disclosure and labelling requirements. The Controlled Substances Act of 1970 saw the regulation of

manufacturers, prescribers, dispensers, and labels, and permitted FDA to require warnings on packages.[30]

59. In the 1990s, FDA began to work with manufacturers to develop risk management programs for drugs with dangerous side effects. Then, in the 2000s, FDA established Risk Minimization Action Plans ("RiskMAPs"), in which manufacturers voluntarily instituted risk minimizing plans.

60. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which codified the Risk Evaluation and Mitigation Strategies ("REMS") to be implemented with respect to certain pharmaceutical products "that have already been approved" and directed the Secretary of Health and Human Services ("HHS") to establish an active post-market drug surveillance infrastructure.[31]

61. A REMS can include, *inter alia,* a medication guide, patient package inserts, and/or restrictions on the distribution of the drug.

62. Since their enactment in 2007, REMS have been increasingly common in FDA's approval process; roughly 40% of new drugs have REMS programs.

63. REMS are intended to give FDA authority to condition drug approval on the implementation of a program designed to address serious risks associated with particular pharmaceutical products. The intention is not to make drugs, or drug samples, less available for appropriate use. In fact, §505-1(f)(8) of the FDAAA explicitly prohibits brand manufacturers from using REMS to "block or delay approval of" an ANDA. The FDAAA does not prohibit the sale of REMS-subject drugs to generic manufacturers that will use those drugs in controlled BE

[30] 21 U.S.C. § 801, *et seq.* (2002).
[31] 21 U.S.C. § 355-1(f)(8).

testing, nor does it give an NDA holder the right to interfere with a competitors' ability to purchase necessary drug samples.

7. Brand Manufacturers Have Abused REMS to Block Generic Competition, Prompting Congressional Action

64. REMS abuse is anticompetitive behavior that unlawfully excludes market entry by generic competitors, costing the U.S. healthcare system more than $5 billion annually.[32] In 2016, Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research ("CDER"), testified that brand companies often use REMS programs "as an excuse to not give the drug to the generics so they can compare it to their drug." This behavior, she noted, causes "barriers and delays in getting generics on the market."[33]

65. On December 20, 2019, Congress enacted material portions of the "Creating and Restoring Equal Access to Equivalent Samples Act of 2016" (commonly known as "CREATES") to combat REMS abuse.[34] CREATES establishes a standalone private right of action for qualifying developers of generic drugs to sue branded drug manufacturers that refuse "to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms."[35] Available remedies include immediate provision of sufficient quantities of samples of the drug on commercially reasonable terms, attorneys' fees and costs, and civil fines "sufficient to deter" a defendant brand manufacturer from withholding samples to other companies developing generics in the future.[36]

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[32] Association for Accessible Medicines, *Increase Competition & Access – Support CREATES Act*, https://accessiblemeds.org/campaign/increase-competition-and-access-rems (last visited Feb. 26, 2019).

[33] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. 31 (2016) (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).

[34] Material portions of CREATES were incorporated into the Further Consolidated Appropriations Act, 2020, Pub. L. 116-94.

[35] 21 U.S.C. § 355-2(b)(1).

[36] 21 U.S.C. § 355-2(b)(4).

66. CREATES establishes a prospective counterbalance to monopolistic schemes by brand manufacturers who abuse the REMS process to unlawfully monopolize the market for a drug by excluding generic competition beyond the period and scope afforded by a lawfully obtained patent, but it does not provide a remedy for past REMS abuse.[37]

8. Citizen Petitions

67. Section 505(j) of the FDCA creates a mechanism that allows a person to file a petition with FDA requesting that the agency take, or refrain from taking, any form of administrative action. Known as a "citizen petition," this regulatory mechanism has also been used by brand manufacturers to unlawfully delay generics.

68. A citizen petition allows a citizen to notify FDA of its genuine concerns about safety, scientific, or legal issues regarding a product at any time before or after it enters the market.

69. Pursuant to FDA regulations, FDA must respond to a citizen petition within 180 days of receipt with a grant in whole or in part, or a denial of the petition. FDA can provide a tentative response with an estimate on a time for a full response.

70. Gary Buehler, R.Ph., former Director of the Office of Generic Drugs ("OGD"), at CDER, noted that of 42 citizen petitions raising issues about the approvability of generic products, "very few . . . have presented data or analysis that significantly altered FDA's

[37] Senator Patrick Leahy's (D-VT) committee comments echo the misconduct alleged against Celgene's here: "The first delay tactic addressed by the CREATES Act involves withholding of drug samples that generic manufacturers need to gain regulatory approval. Federal law requires generic competitors to prove that their low-cost alternative is equally safe and effective as the brand-name drug with which they wish to compete. Unfortunately, some brand-name companies are refusing to provide samples of their product to generic companies for them to make the necessary comparison. This simple delay tactic uses regulatory safeguards as a weapon to block competition." Hearing Before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition," Statement of Senator Patrick Leahy (June 21, 2016), https://www.judiciary.senate.gov/download/06-21-16-leahy-statement-2.

policies." Despite this, it is standard practice for FDA to withhold ANDA approval until it has completed its research into and response to a citizen petition.

71. Responding to a citizen petition strains FDA's limited resources. Regardless of how frivolous a petition may be, FDA must expend considerable resources researching the petition's scientific, medical, legal, and economic issues, and delaying ANDA approval, even if a petition is later found to be baseless.

72. Frivolous petitions sponsored by branded manufacturers have become an increasingly common tactic to delay generic competition.

B. The competitive effects of AB-rated generic and authorized generic competition.

73. Generic versions of brand name pharmaceutical drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is the price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or among generic versions, is price. Typically, generics are 50% to 80% (or more) less expensive than their brand counterparts when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for drug purchasers.

74. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and health insurance create the economic dynamic such that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to

generic purchasing. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market, within the first six months after entry.

1. The first AB-rated generic is priced below the brand.

75. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[38] Every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. Generic sales at lower prices drive a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

76. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market during the 180-day exclusivity period). In the absence of competition from other generics, during the 180-day exclusivity period, a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later generics drive prices down further.

77. Once generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[39]

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[38] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1.

[39] *See, e.g.*, Tracy Regan, Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, The Ongoing Regulation of Generic Drugs, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, Does Regulation Drive Out Competition in Pharmaceutical Markets?, 43 J.L. & ECON. 311 (2000).

78. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months (this percentage erosion of brand sales holds regardless of the number of generic entrants.).[40] In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[41]

3. Authorized generics, like other generics, compete on price.

79. Any 180-day exclusivity period applies to a first-filer ANDA, not to products sold under the authority of the original NDA. As a result, the 180-day exclusivity does not prevent a brand manufacturer from marketing and selling an AG at any time or from licensing another company to do so.

80. The FDA determined that allowing brand manufacturers to introduce AGs during the 180-day exclusivity period is consistent with the "fundamental objective of the Hatch-Waxman [A]mendments" to encourage competition and, as a result, "lower prices in the pharmaceutical market."[42] The FDA reasoned that if a brand releases an AG at a reduced price during the 180-day exclusivity period, "this might reasonably be expected to diminish the economic benefit" to the generic first-filer by increasing competition and causing the generic to

[40] FTC 2011 AG Study at 66-67.

[41] *See* FDA, *What Are Generic Drugs?*, https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs (last updated Aug. 24, 2017).

[42] FDA Response to Mylan and Teva Citizen Petitions at 11-12, Docket Nos. FDA-2004-P-0400 (formerly 2004P-0075) and FDA-2004-P-0146 (formerly 2004P-0261) (July 2, 2004).

"reduc[e] the substantial 'mark-up' [generics] can often apply during the [180-day] period."[43] Such competition, and the resulting price decreases, work to benefit drug purchasers.

81. Brand manufacturers recognize the significant economic advantages of releasing their AGs to compete with the first-filer generic during the 180-day exclusivity period. One study noted that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[44]

82. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period).

83. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[45]

84. The FTC similarly found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average.[46] The first-filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

85. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period. All drug industry participants recognize this.

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[43] *Id.* at 12.

[44] Kevin A. Hassett & Robert J. Shapiro, Sonecon, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 (2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

[45] Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition, and Consumers' Welfare, 26 Health Affairs 790, 796 (2007).

[46] FTC 2011 AG Study at 139.

Brand industry group PhRMA sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic.[47] Generic companies recognize it.[48] Brand companies recognize it.[49]

C. Manipulation of the regulatory structure to impair competition.

86. The brand manufacturer of a pharmaceutical product without generic competition gets all of the profits on all of the unit sales. In this circumstance, brand manufacturers can usually sell their drug for far more than the marginal cost of production, generating profit margins of 70% or more, while making hundreds of millions of dollars in profits. The ability to set price so much above cost is one indication that the brand firm is exercising market power.

87. Competition from generic firms constricts the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were monopoly profits into purchaser savings.

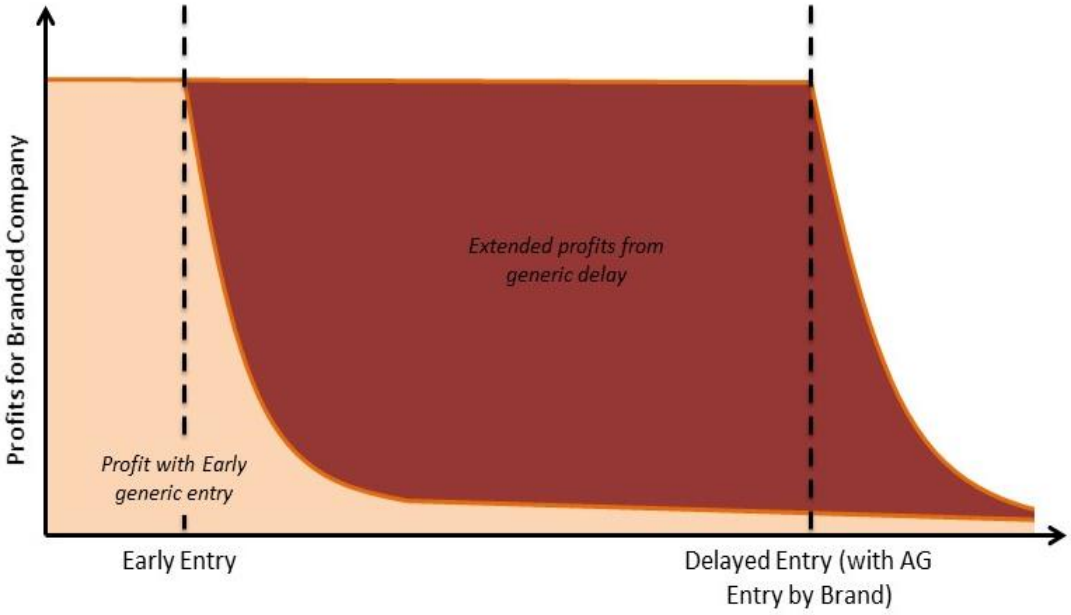
88. While brand manufacturers and first-filer generic manufacturers are typically marketplace competitors, they have a collective interest in preventing robust competition from other generic manufacturers—competition that severely depresses prices—from breaking out. If

[47] IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf.

[48] One generic stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *See* FTC 2011 AG Study at 81. Another generic manufacturer quantified the fiscal consequences of competing with an authorized generic and determined that the authorized generic reduced its first generic's revenues by *two-thirds*, or by approximately *$400 million*. Comment of Apotex Corp. in Support of Mylan Citizen Petition at 4, Docket No. 2004P-0075 (Mar. 24, 2004), https://web.archive.org/web/20041216115511/http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf.

[49] Commenting on an FDA petition by drug manufacturer Teva Pharmaceuticals, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a *flagrant effort to stifle price competition* – to Teva's benefit and the public's detriment." Comment of Pfizer at 6-7, Docket No. 2004P-0261 (June 23, 2004), https://web.archive.org/web/20050601041653/http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/04p-0261-cr00001-01-vol2.pdf; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), https://web.archive.org/web/20041227172543/http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf.

the brand and first-filer generic work together to prevent or delay such competition, they can keep the profit margins high and split the resulting excess profits between themselves. In other words, by stifling competition, the brand manufacturer and first-filer generic manufacturer can maintain high prices, protect their profits, and split between themselves the enormous savings



that increased generic competition would have delivered to drug purchasers.

89. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (i.e., with only an agreed entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly.

90. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide between them the ill-gotten gains—the increased

profit to the detriment of drug purchasers—that delayed competition makes possible. The generic manufacturer has no incentive to refrain from competing unless it shares in the brand profits from delay. To make this happen requires some form of pay offs from the brand manufacturer, resulting in deals that are referred to as "pay-for-delay," "exclusion payment," or "reverse payment" agreements.

91. In the presence of a first filer's 180-day exclusivity period, the brand manufacturer's (unlaw) pay off to the first filer also delays other generic manufacturers from marketing their products: none of the later filers can enter until the first-filer's 180-day exclusivity period has run.

92. Later ANDA filers can expect lower profits than a first filer because they may have little or no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized. As a result, in a pay-for-delay agreement, later-filing generics may require less of a pay not to compete. Under these unlawful arrangements, the brand shares some of its supracompetitive profits with the later-filing generics, and in exchange the later-filing generics to drop their patent challenges and accept a late agreed entry date.

93. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. They extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

1. Manufacturers also use anticompetitive "acceleration" or "most-favored entry" clauses to delay competition.

94. Another weapon in the pharmaceutical monopolist's arsenal is "acceleration" clauses, which often takes the form of a "most-favored entry" (MFE) clause which allows a settling generic to move an entry date earlier based on an agreed-upon or actual date of entry of another generic. When used in settling Hatch-Waxman litigation, MFE clauses dis-incentivize later generic filers from entering the market by eliminating the possibility of a later filer entering prior to any generic (such as but not necessarily the first filer) which has already settled. Furthermore, an acceleration clause transfers value to the settling generic in two ways: the privilege of accelerating based on some contingency increases expected profits, and any deterrent effect on later filers protects the settling generic's market position. Because an acceleration clause creates value for the settling generic, it can be used to induce the settling generic to accept a later entry date.

95. The purpose and effect of an "acceleration" or MFE clause is to dramatically reduce any other generic manufacturer's incentive to try to enter the market as quickly as they can. Absent the "acceleration" clause, other generic manufacturers would have an incentive to enter the market as soon as they were able, thereby enjoying a substantial period as the only ANDA-based generic product on the market. By eliminating this possibility, an "acceleration" clause results in delayed generic entry by, *inter alia*, disincentivizing generics that would otherwise be willing and able to come to market from doing so because of the knowledge that other generics would immediately flood the market.

96. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—twice testified to Congress that "acceleration" clauses represent "the primary anticompetitive aspects of settlements" because they "eliminate any incentive for a

subsequent filer to continue to litigate for earlier market entry."[50] The clauses both induce prospective generic competitors to accept later entry dates and deter others from challenging weak patents:

> "[N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under this system. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch- Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase."[51]

97. Contrary to what their name suggests, in practice, "acceleration" clauses do not accelerate generic entry—they delay it. The evidence for this is conclusive. A recently published study analyzing empirical pharmaceutical settlement data concluded that "[a]n acceleration clause paired with the 180-day exclusivity period appears to effectively deter other generics and, at least in the instances we observed, never to have resulted in an actual 'accelerated' entry." Not once, in cases like this one (Revlimid) where the first-filer retained its 180-day exclusivity, had "acceleration" promoted earlier generic entry. "Among the 54 cases in which the first filer retained sole rights to the 180-day exclusivity period, there were no cases of early generic entry. In other words, there were no cases in which the first filer's entry was accelerated, and there

[50] Protecting Consumer Access to Generic Drugs Act of 2007: Hearing on H.R. 1902 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 110th Cong., at 65, 67 (2007) (statement of Bernard Sherman, CEO, Apotex, Inc.), http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg38992/pdf/CHRG-110hhrg38992.pdf.

[51] Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 111th Cong., at 218 (2009) (statement of Bernard Sherman, CEO, Apotex, Inc.) (hereinafter "Apotex 2009 Statement"), http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf. Apotex addressed acceleration clauses in the context in which, as here, the first-filing generic retained the 180-day exclusivity.

were no cases in which a different generic entered before the entry date set in the first filer's settlement."[52]

VI. FDA REGULATION OF THALOMID AND REVLIMID AND CELGENE'S PATENT PROSECUTION HISTORY RELATED TO THE DRUGS

98. In the mid-20th Century, thalidomide was marketed as a sleeping pill and anti-morning sickness pill for pregnant women. Devastatingly, when consumed by pregnant women, thalidomide caused life-threatening fetal deformities and birth defects. Adverse effects also included nerve damage.

99. Thalidomide was thereafter banned worldwide. The U.S. ban was in place until July 16, 1998, when FDA approved Celgene's December 20, 1996 NDA 20-785 for Thalomid, its branded version of thalidomide. FDA approved Thalomid only as a treatment for ENL, a form of leprosy.[53] To mitigate fetal exposure to the drug, FDA conditioned its Thalomid approval on Celgene's use of the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S.") distribution program, in which patients were required to review educational materials, register with the program, and agree to program restrictions. FDA noted in its Thalomid NDA approval "[t]hat current restrictions strike a balance between the need to prevent fetal exposure to the drug and the need to make the drug available without extraordinary burdens on patients and prescribers."

100. After FDA codified its REMS distribution program, FDA approved Celgene's supplemental NDA containing a proposed REMS program for Thalomid on August 3, 2010.

[52] Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, Journal of Competition Law & Economics, (2020), 16(2), 188-219, 194.

[53] Thalomid was later approved in 2006 to treat Multiple Myeloma ("MM"), subject again to Celgene's restricted distribution system.

101. Celgene filed, prosecuted, and listed in the Orange Book one patent for the Composition of Matter for Thalomid: the '012 Patent, which was first filed with the USPTO in June 2003. Celgene filed, prosecuted and listed a total of fourteen patents in relation to the S.T.E.P.S. and/or REMS programs for controlling Thalomid, and later Revlimid, distribution: the '501 Patent, the '976 Patent, the '432 Patent, the '984 Patent, the '763 Patent, the '188 Patent, the '720 Patent, the '977 Patent, the '784 Patent, the '399 Patent, the '018 Patent, the '566 Patent, the '886 Patent, and the '531 Patent, all of which were filed with the USPTO between August 1998 and August 2012.

102. Revlimid is an immunomodulatory drug that works against cancer cells by affecting the immune system. It is a thalidomide analogue manufactured and marketed by Celgene. On April 7, 2005, Celgene submitted NDA 21-880 to FDA, which provides for the use of Revlimid to treat patients with transfusion dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities. On December 27, 2005, FDA approved Revlimid for this indication. FDA granted Celgene market exclusivity for Revlimid as a new chemical entity ("NCE") until December 27, 2010.

103. Revlimid is subject to a REMS distribution program, RevAssist. The primary goal of the RevAssist program is to prevent fetal exposure to Revlimid. FDA noted in its December 27, 2005 letter to Celgene that RevAssist is "an important part of the post-marketing risk management for Revlimid®."

104. All told, Celgene filed, prosecuted, and listed 30 patents in FDA Orange Book as claiming Revlimid.

105. The Orange Book listed patents for Revlimid included the ’517 Patent, which was first filed with the USPTO in July 1996 (the “’517 patent”), and the two polymorph patents, the ’800 Patent and the ’217 Patent, first filed with the USPTO in September 2004 and December 2008, respectively (the “Polymorph Patents”).

106. Celgene also filed, prosecuted, and listed patents in relation to the RevAssist program for controlling Revlimid distribution: the ’501 Patent, the ’976 Patent, the ’432 Patent, the ’763 Patent, the ’188 Patent, the ’720 Patent, the ’977 Patent, the ’784 Patent, the ’886 Patent, and the ’531 Patent, all of which were filed with the USPTO between August 1998 and August 2012.

107. Celgene also filed, prosecuted, and listed ten patents related to the dosage and methods-of-use for Revlimid: the ’740 Patent, the ’569 Patent, the ’363 Patent, the ’929 Patent, the ’717 Patent, the ’095 Patent, the ’120 Patent, the ’498 Patent, the ’621 Patent, and the ’622 Patent, all filed with the USPTO between April 2003 and September 2014.

108. In 2006, Celgene filed yet another patent, the ’745 Patent, in furtherance of its pattern of erecting an impenetrable “patent fortress” around its Revlimid and Thalomid monopolies.

109. Below is a chart of Celgene’s patent protection web:

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drugs
Composition of Matter						
’517 Patent	5,635,517	24-Jul-96	3-Jun-97	4-Oct-19	Method of reducing TNF.alpha. levels with amino substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisoindolines	Revlimid

’012 Patent	7,230,012	30-Jun-03	12-Jun-07	9-Dec-23	Pharmaceutical compositions and dosage forms of thalidomide	Thalomid
Polymorph						
’800 Patent	7,465,800	3-Sep-04	16-Dec-08	27-Apr-27	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’217 Patent	7,855,217	15-Dec-08	21-Dec-10	24-Nov-24	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid

REMS						
’501 Patent	6,045,501	28-Aug-98	4-Apr-00	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’976 Patent	6,561,976	26-Sep-01	13-May-03	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’432 Patent	6,908,432	22-Jan-04	21-Jun-05	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus	Thalomid Revlimid (Pomalyst)

					or other contraindicated individual to the drug	
’984 Patent	7,874,984	12-Apr-05	25-Jan-11	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid
’763 Patent	8,204,763	13-Dec-10	19-Jun-12	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’188 Patent	8,589,188	17-May-12	19-Nov-13	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid (Pomalyst)
’720 Patent	6,315,720	23-Oct-00	13-Nov-01	23-Oct-20	Methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug	Thalomid Revlimid (Pomalyst)

’977 Patent	6,561,977	27-Sep-01	13-May-03	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
’784 Patent	6,755,784	7-Mar-03	29-Jun-04	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
’399 Patent	6,869,399	22-Jan-04	22-Mar-05	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’018 Patent	7,141,018	3-Jan-05	28-Nov-06	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’566 Patent	7,959,566	19-May-06	14-Jun-11	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid

’886 Patent	8,315,886	13-Dec-10	20-Nov-12	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
’531 Patent	8,626,531	22-Aug-12	7-Jan-14	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid (Pomalyst)
Dosing						
’740 Patent	7,189,740	11-Apr-03	13-Mar-07	11-Apr-23	Methods of using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the treatment and management of myelodysplastic syndromes	Revlimid
’569 Patent	7,968,569	15-May-03	28-Jun-11	7-Oct-23	Methods for treatment of multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’363 Patent	7,468,363	8-Apr-05	23-Dec-08	7-Oct-23	Methods for treatment of cancers using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid

’929 Patent	8,741,929	19-Nov-09	3-Jun-14	8-Mar-28	Methods using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for treatment of mantle cell lymphomas	Revlimid
’717 Patent	8,404,717	24-Mar-11	26-Mar-13	11-Apr-23	Methods of treating myelodysplastic syndromes using lenalidomide	Revlimid
’095 Patent	8,648,095	5-Jun-12	11-Feb-14	15-May-23	Methods for treating multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione in combination with proteasome inhibitor	Revlimid
’120 Patent	9,056,120	13-Mar-13	16-Jun-15	11-Apr-23	Methods of treating myelodysplastic syndromes with a combination therapy using lenalidomide and azacitidine	Revlimid
’498 Patent	8,530,498	8-Apr-13	10-Sep-13	15-May-23	Methods for treating multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione	Revlimid
’621 Patent	9,101,621	17-Apr-14	11-Aug-15	15-May-23	Methods for treating multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione after stem cell transplantation	Revlimid

'622 Patent	9,101,622	10-Sep-14	11-Aug-15	15-May-23	Methods for treating newly diagnosed multiple myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione in combination with dexamethasone	Revlimid
'745 Patent	7,435,745	26-Apr-06	14-Oct-08	31-Jul-19 (Estimate)	Methods and compositions for inhibition of angiogenesis	Thalomid (Not listed in Orange Book)

110. Celgene obtained other patents related to thalidomide and its analogs, but did not list them in the Orange Book.[54] Unlisted patents are not meaningful barriers to generic entry. A brand company does not have standing to sue (and litigate on the merits) a would-be competitor for allegedly infringing an unlisted patent *before* the competitor has actually sold its generic product. Nor do unlisted patents trigger an automatic thirty-month stay of FDA approval for the competitor's ANDA.[55] Celgene ultimately made frivolous infringement claims for unlisted patents in response to ANDAs for lenalidomide, as discussed below.

VII. CELGENE'S ANTICOMPETITIVE SCHEME ILLEGALLY MONOPOLIZED THE MARKET FOR REVLIMID AND THALOMID

[54] That Celgene did not submit these patents for listing in the Orange Book is a concession that they did not meet the statutory standard for listing in the Orange Book or for asserting against a generic company in paragraph IV Hatch Waxman litigation (which triggers the powerfully anticompetitive thirty-month stay).

[55] Unlisted patents can be asserted in infringement suits filed *after* a generic product has launched, in an effort to obtain damages on prior sales. Celgene did not do so here. It is rare that – outside of the Hatch Waxman paragraph IV scheme – a brand company tries to obtain a preliminary injunction to prevent a competitor from launching. Celgene did not do so here. Such motions for preliminary injunctions impose a high standard are regularly denied.

A. Celgene Manipulated FDA's REMS Program as a Pretextual Justification to Refuse Samples Needed to Prosecute ANDAs to Would-Be Competitors

111. Central to Celgene's multi-faceted and decades long scheme to unlawfully monopolize the markets for Revlimid and Thalomid was its REMS abuse. Celgene used its associated REMS distribution programs as a pretext to delay and ultimately refuse to sell samples of Revlimid and Thalomid to competitors that were needed to develop ANDAs, despite exhaustive cautionary measures taken by competitors and comprehensive assurances by FDA. These measures reveal Celgene's claimed business justifications to be entirely pretextual.

1. Celgene's REMS Programs for Revlimid and Thalomid

112. Both Revlimid and Thalomid are subject to REMS distribution programs that require healthcare providers and pharmacies to be certified in the RevAssist or S.T.E.P.S. programs, respectively, and patients to be enrolled in these programs, before prescribing, dispensing, or taking the drugs, respectively. Prescribers and pharmacists must complete registration forms. Women of childbearing age must take a pregnancy test twenty-four hours prior to starting a course of Revlimid or Thalomid and at least every four weeks during their course of treatment. Prescribers must provide patients with contraception and emergency contraception counseling with each new prescription. For every new patient, prescribers must submit to Celgene a signed Patient-Physician Agreement Form that identifies the patient's risk category. The prescriber then receives a letter confirming the patients' enrollment and the patient and prescriber receive an authorization number which is to be written on the prescription. The pharmacy must verify that each prescription has an authorization number that is valid for seven days. The pharmacy must then call Celgene, obtain a confirmation number, and write this number on the prescription. The prescription is then filled within twenty-four hours. No more than a twenty-eight-day supply may be dispensed at one time.

113. The first key to Celgene's monopolistic anticompetitive scheme was to prevent generic manufacturers from obtaining the necessary samples of Revlimid and Thalomid to perform the BE testing needed to file an ANDA.

114. Celgene abused its REMS program as a pretextual justification for withholding Revlimid and Thalomid samples from generic competitors. Among the manufacturers that Celgene refused to supply are Mylan Pharmaceuticals Inc. ("Mylan") between 2004 and the present, Lannett Company ("Lannett") in 2006, Exela Pharmsci, Inc. ("Exela") in 2006, Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009, Watson Laboratories, Inc. ("Watson") in 2009, Teva Pharmaceuticals USA ("Teva") in 2009, and Sandoz Inc. ("Sandoz") in 2012. Celgene also entered into an exclusive supply agreement with a French thalidomide supplier to prevent Barr Laboratories ("Barr") from obtaining that company's thalidomide active pharmaceutical ingredient ("API").

115. Celgene's improper use of the REMS program as a shield to refuse to provide samples is contrary to FDAAA. FDAAA subsection f(8) states that "no holder of [a REMS-covered drug] shall use any element to assure safe use . . . to block or delay approval of . . . an [ANDA application]."[56]

a. Celgene's REMS Programs are Post-Marketing Distribution Systems with No Legal or Practical Relation to Sales of Samples to Competitors

116. Celgene's REMS distribution programs are post-marketing, commercial distribution programs. Celgene's REMS protocols do not discuss drug manufacturers conducting business with one another in the pre-marketing, drug development phase. Nor do Celgene's REMS protocols discuss or prevent distribution of samples to drug manufacturers.

[56] 21 U.S.C. § 355-1(f)(8).

117. Generic manufacturers' safety protocols are not required to be FDA-approved for that manufacturer to purchase samples of a REMS-subject drug. Robert West, former Deputy Director of OGD, commented that "a generic manufacturer is not required to submit its protocols to FDA before commencing bioequivalence studies."[57]

118. Clinical and pre-approval studies are not governed by REMS. In an August 2012 meeting with Celgene, FDA stated, "Celgene's REMS relates to a marketed situation and not a clinical trial where there is more control regarding administration of the product and the amount given is monitored and very limited."

119. A sample supply of a brand-name drug, including the API, is required to manufacture a generic equivalent. The API is used to conduct the required bio-studies and validation testing needed to be included in the generic manufacturer's ANDA.

120. Due to Celgene's REMS program, generic manufacturers are unable to purchase Revlimid and Thalomid samples in the United States through normal wholesale distribution channels. The restricted network that Celgene created forced incumbent competitors to purchase the drugs directly from Celgene, with FDA's endorsement.

b. Celgene Refused to Sell Samples to Mylan

121. Celgene refused to sell Revlimid and Thalomid samples to Mylan, the second largest generic pharmaceutical manufacturer in the world.

122. Mylan began developing a generic thalidomide product on September 26, 2003. On October 27, 2003, Mylan requested OGD to provide guidance on prospective BE studies. OGD provided the requested guidance within the following year.

[57] Exhibit to MSJ Opp., Doc. No. 285-15.

123. On December 22, Mylan requested thalidomide API from API suppliers GYMA Laboratories of America, Inc. ("GYMA") and Antibioticos to manufacture its formulation of thalidomide. By March 11, 2004, Mylan received thalidomide API from Antibioticos.

124. In September 2004, after Mylan was unable to gain access to Thalomid samples, FDA suggested Mylan contact Celgene to request samples. On October 5, 2004, Mylan's attorneys wrote Celgene a letter requesting to purchase 2,500 Thalomid capsules to conduct BE studies. Celgene failed to respond to the letter. Mylan repeated its request on May 3, 2005. By that time, Mylan had already completed safety training sessions for the handling and testing of thalidomide.

125. In a June 21, 2005 letter, Celgene explained that, pursuant to its S.T.E.P.S. program, Thalomid was not available through normal wholesale channels, and that it was against Celgene's policy to deal with third parties in the sale of Thalomid. This policy, to the extent it existed, was pretextual and not based upon any legitimate legal or regulatory concerns.

126. In unsealed internal emails from July 6, 2005, Celgene noted that "Mylan has had difficulty obtaining enough of Celgene's reference product to perform BE studies, so its ANDA submission is expected to be delayed until late in the third quarter of 2005."

127. On September 2, 2005, Mylan directly contacted Celgene and requested to purchase 3,360 Thalomid capsules to conduct BE testing. Mylan explained that the "FDA had recommended that we contact you directly to request a sample" of Thalomid for BE testing, and that "obtaining samples through other traditional channels is nearly impossible."

128. On October 20, 2005, Celgene replied, claiming that it needed additional time to consider the request and "to avoid fetal exposure."

129. On November 15, 2005, Mylan used an intermediary to again request that Celgene sell it Thalomid samples for BE testing.

130. By December 2005, Mylan completed its scale-up of its experimental thalidomide batch. Mylan had, by that time, captured two-years' worth of stability data. The only remaining step to submitting its ANDA was to conduct BE studies against the RLD.

131. On December 19, 2005, Celgene stated that it would need FDA's approval to allow Mylan to purchase samples outside of the S.T.E.P.S. program: "[W]e recommend that you contact FDA's [Division of Special Pathogen and Transplant Products] to discuss the importance of the S.T.E.P.S. program to them." Celgene claimed that if FDA then "contacts us in writing and recommends that we violate our S.T.E.P.S. program by providing you with the quantity of THALOMID you request, we will further evaluate your request at that time."

132. This was puzzling: in an internal report created in 2003 at Celgene's request, Celgene conceded that Mylan's patient monitoring system—already in place for another drug it was studying—was robust, comprehensive, and equivalent to the S.T.E.P.S. program.

133. Celgene's internal report concluded that Mylan's safety protocols "currently have very sophisticated patient monitoring systems for their respective clozapine products."[58] The report also stated "it can be observed that the clozapine requirements are as comprehensive as the S.T.E.P.S. program. Thus, Ivax and Mylan already have experienced [sic] with sophisticated monitoring systems."[59]

[58] Exhibit to MSJ Opp., Doc No. 286-1.
[59] *Id.*

134. Next, Mylan requested FDA assistance to obtain the necessary Thalomid samples required for bioequivalence testing on January 11, 2006. In its letter, Mylan proposed protocols to ensure avoidance of fetal exposure.

135. On February 12, 2007, FDA replied, requesting an investigational new drug application ("IND") or study protocol so that it could "ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place," as a substitute for the S.T.E.P.S. program.

136. FDA's response continued:

> It is FDA's view that certain restrictions are needed to ensure safe use of the drug; however, it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product. The agency believes that such bioequivalence studies can be conducted safely under either an IND or in circumstances that provide alternative assurance of patient safety. To ensure that the intention of Congress in enacting the generic drug approval provisions in section 505(j) is not frustrated by the terms of the S.T.E.P.S. program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid (including 200 units for the purpose of conducting bioequivalence (including dissolution) testing and 300 units for a limited number of retained samples) when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects.

137. On May 1, 2007, Mylan produced to FDA its proposed thalidomide safety protocols, which FDA reviewed, found "acceptable," and so notified Mylan on September 11, 2007.

138. On November 16, 2007, Mylan notified Celgene of FDA's approval, which directly addressed Celgene's pretextual justification for not providing samples. Celgene's senior executives and officers all admit that FDA is the ultimate authority on setting safety standards.

Yet Celgene continued to deny Mylan's and others' requests for drug samples for BE testing, using pretextual and obviously flawed safety concerns as its chief justification.[60]

139. Undeterred, Mylan continued to make requests over the next three years, including on December 4, 2007. Celgene continued to refuse to produce Thalomid samples, using delay tactics including requiring Mylan to produce burdensome, irrelevant, and duplicative information. Meanwhile, Celgene internally admitted that another prospective ANDA filer's request was "deficient in a way that the Mylan request is not."

140. On January 8, 2008, Celgene wrote Mylan requesting more information. Mylan responded on February 25, 2008 writing that it was prepared to provide all requested information and enclosed a confidentiality agreement. Celgene and Mylan negotiated the confidentiality agreement until June 24, 2008, when Celgene sent Mylan the executed agreement. Mylan sent Celgene another letter providing even more information and provided Celgene with proof of liability insurance covering any instances of injury relating to the drug's misuse, and further provided an indemnity contract.

141. This contract, which was extensively negotiated, agreed to hold Celgene harmless in the event of any injury or misuse.

142. Celgene wrote Mylan on August 1, 2008 that it was reviewing Mylan's documentation. Celgene's then-Regulatory Counsel testified that as of March 4, 2011, no "business people" at Celgene reviewed any of Mylan's documentation. Confoundingly, Celgene served an interrogatory response in an FTC investigation that two former CEOs, Sol Barer and

[60] On April 21, 2000, FDA sent Celgene a "Warning Letter" stating that "Celgene has engaged in promotional activities that state or suggest that Thalomid is safe and effective for use in treating multiple myeloma." With no generics on the horizon, Celgene was willing to play fast and loose with the safe distribution of Thalomid so long as it ensured increased utilization and increased profits.

Robert Hugin, "made the decisions on behalf of Celgene regarding Celgene's responses to pharmaceutical companies requesting to purchase Revlimid® and Thalomid® with legal advice from Celgene's Deputy General Counsel and then-Regulatory and Compliance Counsel." The referenced in-house counsel later testified in a separate litigation that they did not have any input into the requests, and could not recall reviewing a single response to one of the information requests submitted to Celgene, or sitting in a meeting in which a response to a prospective ANDA filer's request was discussed. Upon information and belief, Celgene lied to the FTC in its interrogatory response.

143. Celgene wrote Mylan in a June 24, 2009 letter that there were "outstanding issues" with the information Mylan provided and requested nine additional categories of information. An internal Celgene email dated May 22, 2009 contained a project titled "Thalidomide Multiple Myeloma." The summary of the project stated "A generic thalidomide application was successfully delayed until at least June '09 in the USA. Celgene may further extend its exclusivity in the USA by using bioequivalence as a generic defense strategy…." Celgene's own emails show that it was never truly concerned with the safe distribution of its drugs, but rather used safety as a pretextual justification to prevent generic competition.

144. Celgene's refusal to sell Mylan samples, despite the existence of liability insurance and an indemnity contract, is further evidence Celgene was unwilling to negotiate in good faith with generic manufacturers to provide the requested drugs. This Court previously held, based on these facts, that one could reasonably infer "that Celgene had no objectively

legitimate business justification for not selling Mylan samples of Thalomid® or Revlimid® samples after FDA approval of Mylan's study protocols."[61]

145. Celgene's refusal to supply Mylan and other competitors with samples prompted government investigations and persistent condemnation, which occurred concurrent to Mylan's commercial and legal attempts to secure samples, as described more fully below. FDA issued official clarifications that REMS programs should not be used for anticompetitive reasons,[62] and specifically included Revlimid and Thalomid on a publicly published list of brand-name drugs that had been the target of complaints that their NDA-holder (or manufacturer) is and/or had been denying access to samples of RLDs when generic companies seek to buy them.[63] The Connecticut Attorney General's office initiated an investigation into Celgene's alleged REMS abuse relating to Revlimid and Thalomid, and wrote in January 2013 that Celgene's responses to its REMS abuse inquiry "ha[ve] raised serious concerns in my office that, notwithstanding its claims to the contrary, Celgene is not truly willing to sell Revlimid samples in a manner that would allow the BE testing necessary for a competitor to submit an ANDA….Celgene's current actions raise the specter that the discussions have been nothing but an artifice to continue to

[61] *Mylan Pharma Inc. v. Celgene Corp*., No. 14-cv-2094, ECF No. 287, 35 (D.N.J. Oct. 3, 2018).

[62] *See* Center for Drug Evaluation and Research, FDA, Risk Evaluation and Mitigation Strategy (REMS) Public Meeting (July 28, 2010), at 270-71 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research).

[63] FDA received numerous access inquiries for Celgene's Thalomid, Revlimid, and a third drug not subject to this Complaint, Pomalyst (pomalidomide). The list documents that FDA received ten inquiries related to Thalomid, thirteen inquiries related to Revlimid, and eight inquiries related to Pomalyst. FDA issued at least four safety letters for Revlimid, including on July 21, 2012, May 19, 2014, February 22, 2017, and August 15, 2017. FDA issued safety letters for Thalomid on December 12, 2007, and January 17, 2008.

allow Celgene to delay the development of a generic alternative to Revlimid."[64] Additionally, as mentioned above, the FTC investigated and served interrogatories on Celgene regarding its REMS abuse, wrote an amicus brief in support of Mylan's antitrust suit against Celgene, and later began to regularly testify before Congress raising the alarm regarding REMS abuse by Celgene and others,[65] and ultimately submitted statements to the Department of Health and Human Services ("DHHS") urging action.[66]

146. Mylan estimates that had Celgene provided it with Thalomid samples in 2006, it would have filed a Paragraph IV Certification, Celgene would have initiated a patent infringement litigation and Mylan could have ultimately entered the thalidomide market in the third quarter of 2010.

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[64] *See e.g.*, Exhibit to MSJ Opp., Doc. No. 285-21 ("[d]espite clear guidance from both Congress and FDA that drug firms should not use REMS programs to block or delay generic or biosimilar competition, complaints about abuse of the regulatory process persist . . . One study estimates that Americans have lost $5.4 billion in annual savings due to delays in accessing drug samples caused by REMS misuse and other non-FDA mandated restricted distribution programs.").

[65] *Antitrust Concerns and FDA Approval Process*, Prepared Statement Markus H. Heier, Bureau of Competition, Federal Trade Commission before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Judiciary Committee, United States House of Representatives, Washington, D.C. (July 27, 2017), https://www.ftc.gov/public-statements/2017/07/prepared-statement-federal-trade-commission-antitrust-concerns-fda; *Oversight of the Enforcement of the Antitrust Laws*, Prepared Statement of the Federal Trade Commission before the Subcommittee on Antitrust, Competition Policy and Consumers Rights, Judiciary Committee, U.S. Senate (Oct. 3, 2018).

[66] *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, Statement of the Federal Trade Commission to the U.S. Department of Health and Human Services (July 16, 2018), *available at* www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-humanservices-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf. ("[b]y improperly blocking the product developer from obtaining samples, the branded manufacturer can potentially delay or indefinitely block generic or biosimilar competition to its product, thereby reducing the competition that Congress specifically sought to facilitate via the Hatch-Waxman Act . . . .").

147. By June 2007, Mylan began to develop its generic Revlimid. In internal emails from September 2007, Mylan planned to file its ANDA on December 27, 2009, was actively sourcing raw materials, had opinions on the blocking compound patents, and planned to design around the formulation patent.

148. In early 2009, Mylan endeavored to purchase lenalidomide supplies to manufacture a generic version of Revlimid. Celgene engaged in more delay tactics, causing Mylan to cease development efforts at various points while it attempted to procure Revlimid samples. Mylan manufactured its final lenalidomide formulation in June 2015.

149. In June 2010, in response to FTC interrogatories, Celgene explained to the FTC that "Celgene has decided not to sell REVLIMID® at the present time to manufacturers."[67]

150. Over two years later, through its counsel, Celgene wrote to the FTC that it was willing to "continue selling Thalomid and begin to sell Revlimid to drug companies, branded or generic, in quantities authorized by FDA sufficient to conduct bio equivalence studies for the purpose of preparing an Abbreviated New Drug Application [ANDA] with FDA."[68] Celgene, at no point prior to this email, ever sold Thalomid to generic drug companies to support BE studies for the purpose of preparing ANDAs. Celgene's letter continued: "[Celgene would] seek to set appropriate conditions with FDA for the sale of Revlimid similar to those it has set for the sale of Thalomid . . . ."

151. On August 14, 2012, Celgene wrote FDA claiming that the FDCA does not require an RLD sponsor to provide drug product to a proposed ANDA filer, and that FDA does not have authority to mandate any such requirement. Celgene even threatened that "any sale of

[67] Exhibit to MSJ Opp., Doc No. 286-4.
[68] *Id.*

Revlimid to a generic manufacturer will not be effectuated unless and until the FTC and the State of Connecticut Attorney General agree to close their investigation."[69]

152. On May 1, 2013, Mylan requested to purchase Revlimid samples from Celgene at market value. On May 14, 2013, Celgene wrote to Mylan that it would sell Revlimid to Mylan upon Celgene's review of Mylan's request and supporting documentation.

153. While not required to do so, Mylan sought FDA approval of its proposed safety protocols to avail itself of any assistance FDA might be able to offer in procuring Revlimid samples. FDA approved Mylan's protocols on July 29, 2013.

154. On March 11, 2014, Mylan wrote to Celgene explaining that it received all necessary FDA approvals. Celgene continued to refuse to provide samples, even, once again, after being informed of FDA approval for the proposed BE testing and safety protocols.

155. On March 20, 2014, Celgene again wrote to Mylan refusing to sell Mylan Revlimid samples. Exasperated with Celgene's tactics, Mylan brought a suit on April 3, 2014 against Celgene under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly power in the market for Thalomid and Revlimid.

156. Mylan alleged that Celgene cited safety concerns as a pretext for its continued refusal to provide samples of Thalomid and Revlimid, and that Celgene used a "playbook of obstruct[ion]" and "gam[ed] the regulatory system."[70]

157. On May 19, 2014, FDA notified Celgene that it accepted Mylan's submitted lenalidomide safety protocols and reiterated the FDCA's prohibition of using REMS to prevent ANDA filers from accessing drug samples.

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[69] Exhibit to MSJ Opp., Doc No. 285-15.

[70] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094 (D.N.J. Apr. 3, 2014), Dkt. No. 1 ¶8.

158. The FTC filed an amicus brief in support of Mylan's suit against Celgene. The FTC noted that FDAAA was intended to prevent brand-name manufacturers from using REMS programs to impede generic competition, as Celgene was doing with Thalomid and Revlimid.

159. Further, in August 2012, the FTC sent counsel for Celgene an email detailing "a number of questions [raised] by the Bureau of Competition and the staff of the Connecticut Attorney General's office."[71]

160. These concerns included questions surrounding why Celgene had yet to provide samples of Thalomid to those requesting it, despite receiving explicit authorization from FDA to do so.

161. The letter also questioned what else Celgene would need to receive in order to authorize the sale of Revlimid to generic manufacturers: "in the interest of advancing our discussions and trying to reach a prompt resolution with you, we propose the FTC and Celgene meet together with FDA . . . to discuss what Celgene thinks it needs from FDA in order to be able to make prompt sales to generic firms."[72]

162. The FTC's Bureau of Competition ("BOC") followed up on this letter with another round of correspondence in February 2013.

163. In a letter to Celgene's counsel, Richard A. Feinstein, the director of the BOC stated "that there is a lot of concern here—at both the Bureau and Commission levels—about the time it has taken for your client to [redacted] of Revlimid capsules for bio-equivalence testing…the Commission's patience is wearing thin. We have reached a point where the staff may be instructed in the very near future to commence litigation."

[71] Exhibit to MSJ Opp., Doc No. 285-16.
[72] *Id.*

164. Counsel for Celgene quickly forwarded this email to Celgene executives.

165. Most of Mylan's claims survived Celgene's motion to dismiss. Celgene subsequently filed its motion for summary judgment. On October 3, 2018, Celgene's motion was granted-in-part and denied-in-part.[73]

166. One of Mylan's expert witnesses in that litigation, Paul J. Jarosz, Ph.D., testified that Mylan's development process was typical for the pharmaceutical industry and that "[h]ad Mylan been able to purchase Thalomid so that it could dose its bioequivalence studies and receive an approval for its generic drug application, Celgene's '012 Patent and claim 2 of its '327 Patent would not have prevented Mylan from launching its generic thalidomide product as the claims are invalid due to prior art and/or Mylan's formulation does not infringe them."[74]

167. Regarding generic Revlimid, Dr. Jarosz stated that "based on the simple nature of Revlimid and Mylan's previous experience developing thalidomide, it appears that Mylan could have developed and filed an application for generic lenalidomide product by December 27, 2009."[75]

168. Dr. Jarosz's report confirms that the inability of generic drug manufacturers to bring versions of Revlimid and Thalomid to market was not due to internal issues or manufacturing defects. Instead, his report reinforces the fact that the only barrier to entry in the market was Celgene's conduct.

169. Mylan never received Revlimid samples, further indicating that Celgene's refusal based on safety concerns was and continues to be a pretext used to exclude competition.

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[73] *Mylan Pharma Inc. v. Celgene Corp*., No. 14-cv-2094, ECF No. 287, 35 (D.N.J. Oct. 3, 2018).

[74] Exhibit to MSJ Opp., Doc No. 285-21.

[75] *Id.*

170. On August 1, 2019, Celgene announced that it reached a settlement with Mylan. On August 8, 2019, the District Court entered a consent judgment dismissing all claims with prejudice. Celgene disclosed that it agreed to pay $62 million to resolve all claims.

171. Due to Celgene's delay tactics, Mylan was not able to file an ANDA for generic lenalidomide and serve its Paragraph IV notice until November 2019. *See infra*, Part VII.E.i.5.d. But for Celgene's anticompetitive scheme, Mylan would have launched a generic competitor.

i. Mylan's Strong Safety Protocols Confirm and Illustrate the Pretextual and Unlawful Nature of Celgene's Refusal to Sell Samples to Would-Be Competitors

172. Mylan's experience with the REMS process was robust and extensive, and it would have had no issues implementing one for generic thalidomide and lenalidomide.[76] As another expert hired by Mylan in its lawsuit against Celgene, Jeff Fetterman, opined, "Mylan has extensive experience developing, implementing, and managing risk management programs, including several REMS programs with the same or similar restrictions and requirements as the S.T.E.P.S. and RevAssist programs."[77] Mr. Fetterman continued and stated "[i]f Celgene had provided brand samples to Mylan and cooperated in developing a shared REMS program for thalidomide, the SS REMS development and FDA approval likely would have taken 18 to 24 months. Furthermore, this estimate may be conservative, as an alternative parallel agreement to sign onto the S.T.E.P.S. program would have taken even less time, possibl[y] in as few as 12 months. All of this work could have begun in advance of Mylan's ANDA approval…."[78] Mr. Fetterman's report details further how Celgene's refusal to provide drug samples due to

[76] Exhibit to MSJ Opp., Doc No. 286-2.
[77] *Id.*
[78] *Id.*

noncompliance with REMS procedures was a misdirection and stall tactic that was not based in truth or fact.

173. By contrast, Mylan's discussions with Sofgen Pharmaceuticals ("Sofgen") surrounding the purchase of Mylan's Amnesteem show that receiving an FDA approval letter removes any perceived roadblocks to sharing a drug sample for BE testing. In September 2011, Sofgen contacted Mylan regarding the potential purchase of Amnesteem for BE testing, a known human teratogen under FDA restriction for sale and delivery. Prior to contacting Mylan, Sofgen reached out and received a letter from FDA confirming its iPLEDGE safety restrictions and procedures were adequate under current FDA guidelines to receive a human teratogen. Mylan and Sofgen entered into successful negotiations, drafted an indemnity agreement, and discussed the purchase price and the method for payment and delivery. The sale was completed, and samples were delivered to Sofgen in Spring 2013. Mylan's contract with Sofgen shows the process for obtaining generic drug samples can be completed in a short timeframe, and without the unnecessary and burdensome documentation Celgene requested from numerous generic manufacturers.

c. Celgene Refused to Sell Samples to Exela

174. On May 31, 2006, Exela contacted Celgene and informed it of Exela's intention to file an ANDA for Thalomid. Exela stated it was having difficulty obtaining samples of this drug from other channels, much like the other generic manufacturers who had contacted Celgene. Exela requested a proposal for purchase within 10 days.

175. On June 27, 2006 Exela sent a follow-up letter to Celgene again requesting to purchase Thalomid samples. In its letter, Exela noted the 10-day window for a purchase proposal had lapsed despite being received the day after it was sent.

176. On September 11, 2007, OGD wrote to Exela that its "proposed bioequivalence study protocol comparing Thalidomide Capsules, 200 mg to [Thalomid] is acceptable . . . ."

177. On December 11, 2007, OGD Director Gary J. Buehler sent a letter to Celgene's internal regulatory counsel, Kerry Rothschild stating that "FDA has reviewed the bioequivalence protocol submitted . . . on behalf of Exela and has received sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects and has determined that Celgene may provide Exela with 500 units of Thalomid as indicated in FDA's letter to you dated February 8, 2007 for the purposes of conducting an *in vivo* bioequivalence study and *in vitro* dissolution testing."

178. Over a year later, on January 8, 2008, counsel for Celgene contacted counsel for Exela regarding the Thalomid purchase request.

179. In a response almost identical to ones given to other generic manufacturers, Celgene stated it did not believe it was obligated to turn over any samples. However, it continued, if Exela were to comply with a list of 10 demands for information, including, for example, proof of liability insurance and a history of product loss due to improper handling or tracking, Celgene would then "reconsider" its denial. Upon information and belief, Celgene never provided Exela with the requested samples of Thalomid.

d. Celgene Refused to Sell Samples to Lannett

180. On September 6, 2006, Lannett wrote a letter to FDA requesting BE recommendations regarding thalidomide capsules.

181. FDA's OGD responded to Lannett's letter on February 12, 2007. The OGD stated that "it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence

testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product."

182. The OGD commented that, to ensure Congress' intentions in enacting the Generic Drug Approval Provisions in Section 505(i) are carried out, "FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid . . . for the purpose of conducting bioequivalence testing."

183. On February 8, 2007, FDA notified Celgene that "a study protocol would be reviewed by FDA to ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place" if a proposed generic manufacturer wished to conduct BE studies. FDA explained that it would "exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid for the purpose of conducting [BE] testing, when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the [BE] study will be conducted in such a manner as to ensure the safety of the subjects."

184. FDA's letter also requested Celgene submit a supplement to its own Thalomid NDA to the same effect. Celgene failed to submit this supplement, evidencing its own disregard for safety, non-monetarily incentivized circumstances.

185. Nevertheless, Celgene's then-regulatory counsel Kerry Rothschild testified that FDA's February 8, 2007 letter did not fully assuage Celgene's worry that a fetal exposure and birth of a baby with thalidomide-recognizable defects would have consequences to the value of

Celgene's business.[79] Celgene Chief Executive Officer, Mark Alles, testified in 2016 that of the small number of fetal exposures to Thalomid between its development and 2016, the exposures "had minimal impact on the business as far as I know . . . ."[80]

186. In a July 26, 2007 letter to Celgene, Arthur P. Bedrosian, President and CEO of Lannett, wrote:

> In order to complete our bio-study, FDA has instructed us to purchase 250 Thalomid 200 MG Capsules from you. We kindly request information as to how to best carry out this transaction. We will be happy to supply a purchase order once you provide us with the total product cost. Submitted with this document, you will find the appropriate licenses necessary for us to purchase the product from you. We kindly ask that you inform us of any additional information you will need to complete this transaction.

187. Upon information and belief, in September 2007, Lannett faxed to Celgene's Darnell Ragland, Manager, Customer Care of Celgene, a requested copy of the February 12, 2007 FDA letter, which authorized Lannett to acquire Thalomid supplies from Celgene.

188. Celgene continued to refuse Lannett's request. Celgene even went as far as actively screening any communication from Lannett directed towards Celgene regarding requests for samples of Thalomid.

189. In a September 28, 2007 internal email (only made publicly available in redacted form in 2018), a Celgene training alert ordered employees "**DO NOT PROCESS THE ORDER**" (emphasis in original) if a generic company calls or writes requesting to order Thalomid. Instead, the call center employees were directed to log the call, advise that a management team member would return the call, and to never transfer the call to someone higher up.

[79] Exhibit to MSJ Opp., Dkt. No. 285-1 at 36-27.
[80] Exhibit to MSJ Opp., Dkt. No. 286 at 185-186.

190. Employees were further instructed to forward any similar correspondence via fax to one of their supervisors.

191. Then, on October 18, 2007, Lannett wrote a letter to Mr. Ragland reiterating Lannett's request so that it could conduct BE testing needed to obtain approval to market its generic thalidomide.

192. On January 8, 2008, Celgene advised Lannett that it would not provide samples of Thalomid to Lannett. Rather, Celgene requested Lannett produce voluminous and unnecessary documentation in order for Celgene to "reconsider" the request.

193. On January 14, 2008, Lannett filed a complaint against Celgene seeking, among other things, mandatory injunctive relief requiring Celgene to provide samples of Thalomid as contemplated by the February 12, 2007 FDA letter.[81] The case was dismissed without prejudice.

194. Lannett then provided almost all of the information that Celgene requested except its highly confidential FDA Form 483 inspection reports, which relate to the routine inspection of manufacturing facilities, given that the Thalomid samples Lannett requested would not be used for manufacturing, but rather for BE studies that it would perform overseas.

195. Lannett submitted its proposed study for FDA review, and received approval on August 11, 2008.

196. Lannett refiled its Complaint on August 15, 2008 alleging violations of the Sherman Act and seeking injunctive relief. Celgene filed its motion to dismiss on November 4, 2008. Celgene sought, in the alternative, a stay of the action pending resolution of its Citizen

[81] *Lannett Company, Inc. v. Celgene Corp*., No. 08-cv-0233. (E.D. Pa.).

Petition. Celgene argued that it had no obligation to sell Lannett samples because it believed that there should be no generic competition for Thalidomide in the United States *at all*.[82]

197. While the motion to dismiss was pending, the parties reached a settlement agreement for Celgene to provide Lannett with samples in July 2009. When Celgene continued to decline to supply the samples, litigation renewed, with Celgene renewing its arguments that there should be no generic competition for Thalidomide.

198. Celgene's motion to dismiss or stay the proceeding was summarily denied without prejudice on May 13, 2010,[83] and again summarily denied on March 31, 2011.[84]

199. A week before summary judgment briefs were due, the court held a settlement conference on December 1, 2011, at which Celgene reached a confidential settlement with Lannett and the action was dismissed.

200. Celgene reached a confidential settlement with Lannett in 2011.

201. In its 2012 Annual Report, Lannett stated that "a sizable portion of our fiscal 2013 R&D budget is earmarked for two large market opportunity projects, C-Topical and Thalidomide." Its 2013 Annual Report stated that Lannett "successfully passed critical milestones for submitting a product application for Thalidomide." As discussed below, Lannett eventually filed a thalidomide ANDA in late 2014.

202. Upon information and belief, the settlement between Celgene and Lannett may have contained anticompetitive terms, such as a promise to delay submission of the ANDA.

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[82] Motion to Dismiss, *Lannett Co., Inc. v. Celgene Corp.*, No. 08-cv-3920, ECF No. 12 (E.D. Pa. Nov. 4, 2008).

[83] Order, *Lannett Co., Inc. v. Celgene Corp.*, No. 08-cv-3920, ECF No. 27 (E.D. Pa. May 13, 2010).

[84] Order, No. 08-cv-3920, ECF No. 42 (E.D. Pa. Mar. 31, 2011) (denying renewed motion to dismiss).

203. The anticompetitive effect of Celgene's conduct was to delay Lannett's ANDA. Though Lannett began requesting Thalomid samples in 2006, it was unable to obtain such samples due to Celgene's delay until at least after December 2011 and did not file its ANDA until 2014, at which time Celgene filed a sham patent litigation, discussed below, all to delay Lannett's thalidomide product. As of today, there is no generic thalidomide on the market.

e. Celgene Refused to Sell Samples to Dr. Reddy's

204. Dr. Reddy's is a prescription drug manufacturer based in Telengana, India. It has been developing generic prescription drugs for sale in the United States since 1994.

205. Dr. Reddy's requested samples of Revlimid from Celgene to perform BE testing in August 2008. Celgene did not reply to this request.

206. Dr. Reddy's repeated its request in December 2008. Celgene offered a single sentence reply in January 2009: "Celgene has no obligation to supply Dr. Reddy's with Revlimid and declines to do so."

207. In its request to Celgene, Dr. Reddy's assured Celgene any testing it performed would comply with FDA guidelines, using methods similar to Celgene's REMS program known as RevAssist to insure proper handling of the subject drugs.[85]

208. Dr. Reddy's filed a citizen petition with FDA in June 2009, alleging that Celgene was refusing to provide samples to a generic drug manufacturer to perform BE testing.

209. Celgene once again premised its refusal on its REMS program, despite FDA's previous guidance.

210. In 2016, Dr. Reddy's filed an ANDA for a generic lenalidomide product. As discussed below, Celgene then sued Dr. Reddy's claiming patent infringement.

[85] Exhibit to MSJ Opp., Doc No. 285-6.

f. Celgene Refused to Sell Samples to Teva

211. Teva requested a total of 5,000 Revlimid Capsules in 5, 10, 15, and 25 mg dosages from Celgene to perform BE testing in March 2009.

212. In its letter to Celgene, Teva stated that its ". . . procedures for conducting any required testing involving lenalidomide and the Revlimid drug product provided by Celgene Corporation will fully comply with FDA requirements. Teva's controls with respect to lenalidomide will be comparable to the RevAssist program."

213. In April of 2009, Celgene responded to Teva's request, and in a one sentence reply, stated "[t]his letter is to inform you that your request for 5,000 capsules of REVLIMID (lenalidomide) in varying strengths is declined."

214. Celgene's refusal to provide Teva with samples of Revlimid follows a similar course of conduct as with refusals to other generic pharmaceutical companies.

g. Celgene Refused to Sell Samples to Watson

215. In June of 2009, much like the other generic manufacturers described above, Watson contacted Celgene to acquire samples of Revlimid and Thalomid for BE testing.

216. In its request, Watson assured Celgene the process by which it would handle the samples of these drugs would fully comply with a restricted distribution system similar to RevAssist.

217. Furthermore, Watson assured Celgene that FDA guidelines would be followed, and no drug would be distributed in violation of these guidelines, which would have been unlikely to happen given Watson's vast experience and expertise in the generic drug manufacturing market.

218. In July 2009, despite Watson's assurances that the requested samples would be handled in a safe, effective, and FDA-compliant manner, Celgene responded with a list of 10

pieces of evidence and documentation Watson would need to provide before Celgene would consider Watson's request. Celgene indicated it would respond to Watson's request for Revlimid in a separate letter.

219. Tellingly, Celgene did not say satisfying these 10 requirements would facilitate a prompt sale of the samples, merely that at that time Celgene would "consider" it.

220. Upon information and belief, like the generic manufacturers before and after, Watson was unable to obtain the samples of Revlimid and Thalomid it requested, with no logical reason provided.

h. Celgene Refused to Sell Samples to Sandoz

221. In May of 2012, much like the other generic manufacturers described above, Sandoz contacted Celgene attempting to acquire samples of Revlimid and Thalomid for BE testing.

222. In response, Celgene refused to provide the samples, and instead listed nine prerequisites Sandoz had to satisfy before it would consider selling the requested samples.

223. These prerequisites included that Sandoz provide "Proof of liability insurance sufficient to cover events associated with thalidomide and lenalidomide," "[p]olicies for biohazard handling, disaster recovery plans as well as the storage and use of teratogenic products," and "[w]ritten confirmation that an IND is in effect or a study protocol . . . has been approved by FDA."

224. Like its correspondence with other generic manufacturers wishing to obtain drug samples, Celgene referenced the REMS procedures as a reason it could not immediately supply Sandoz with samples, despite FDA approval of Sandoz's procedures.

225. Upon information and belief, like the generic manufacturers before it, Sandoz was unable to obtain the samples of Revlimid and Thalomid it requested.

226. Celgene has provided Revlimid and/or Thalomid to no generic manufacturer.

2. Celgene Had No Legitimate Business Justification for Refusing Samples to Would-Be Competitors Because Its Safety Concerns Were Pretextual

227. While Celgene refused to supply any potential ANDA sponsor the necessary and required samples of Revlimid and/or Thalomid based on safety concerns, it authorized its competitive intelligence firm, GBMC, to purchase, handle, and transfer thalidomide with no safety training required.

228. In 2003, Celgene authorized GBMC to purchase thalidomide API from a European supplier, Alan Pharmaceuticals. In fact, GBMC was authorized by Celgene to use undercover purchases to obtain samples of thalidomide API from various API suppliers. In an undated letter, GBMC detailed the sequence of events it used to acquire, at Celgene's request, thalidomide samples outside the normal chains of distribution. This sequence included falsifying prescriber names and permitting GBMC (a non-pharmaceutical company with no experience in handling teratogenic drug product) to handle thalidomide samples, all without a formal tracking mechanism. Celgene's Senior Director of Market Research testified in a previous litigation that he did not notify Celgene's legal department of these undercover purchases, that Celgene did not do background checks on individuals that would be handling the drug product, and that he could not recall whether the purchased product was in its proper packaging when Celgene received it, or who at Celgene received it.

229. These Celgene authorized transactions did not comport with any safety protocol.

230. Celgene willingly and frequently provided access to Revlimid and Thalomid to non-competitor research organizations, outside the REMS process and without FDA guidance or approval for the safe handling of the drug products, for the purpose of conducting clinical studies.

231. Celgene provided Revlimid for at least 3,600 different research and investigational studies all of which operated outside the REMS process. Celgene similarly provided Thalomid for over 100 investigator-initiated trials ("IIT").[86]

232. For example, Celgene provided Revlimid and Thalomid to the Johns Hopkins School of Medicine for clinical trials and provided Revlimid to Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute, Eastern Cooperative Oncology Group, Mayo Clinic, and MD Anderson Cancer Center in Houston, TX.

233. An IIT process is initiated when an investigator submits a Letter of Intent ("LOI") outlining a proposal. The brand company, here Celgene, then reviews the proposal. Celgene testified that it tried not to review the full protocol, but rather would typically review a simplified synopsis, along with the nature of the request, the budget, and the amount of drug requested. The request, typically adjudicated within two months, does not require in-house counsel assistance. Celgene has never denied an IIT proposal due to fetal exposure safety concerns.

234. After approving an IIT proposal, Celgene works with the investigator to draft a study protocol and consent form which then is submitted to FDA for approval. In this specific context, Celgene had admitted that FDA's approval gives Celgene confidence in the safety of the trial. Celgene then supplies Revlimid or Thalomid to the investigator to initiate the study.

[86] IITs are clinical studies initiated and managed by non-pharmaceutical company researchers, such as individual investigators, institutions, collaborative study groups, cohorts or physicians.

B. Celgene Induced API Suppliers into Anticompetitive Exclusive Contracts to Exclude Competing Generic Manufacturers from Accessing API Needed to Develop Revlimid and Thalomid

235. As part of its multi-faceted and decades long scheme to unlawfully monopolize the markets for Revlimid and Thalomid, Celgene not only refused to sell samples to competitors, it also executed exclusive contracts with ingredient suppliers designed to delay competitors from obtaining the needed resources to file an ANDA. As Celgene could not exhaust API supply from these suppliers, the exclusivity provisions had no business justification and were executed entirely to deny competitors access to API, thereby foreclosing generic entry into the Revlimid and Thalomid markets. On information and belief, Celgene prevented Barr Laboratories, Inc. ("Barr"), a generic drug manufacturer, from obtaining API supply from Seratec, and Plaintiff believes that after a reasonable opportunity for discovery it may uncover more anticompetitive exclusive contracts.

236. After FDA approved Celgene's Thalomid, Barr sought to develop a generic version of thalidomide. In order to secure approval of an ANDA, a proposed generic manufacturer must designate the API manufacturer in the ANDA. The ANDA applicant must submit a Drug Master File ("DMF") from the API supplier to FDA, which is evaluated with the ANDA.

237. In approximately 2004, Barr succeeded in procuring thalidomide API from Seratec S.A.R.L. ("Seratec"), a French supplier, to develop a generic version of Thalomid by September 2005. Barr submitted its ANDA to FDA and was waiting to receive a DMF letter from Seratec.

238. Barr's ANDA proposed a skinny label, only seeking approval for ENL, and not MM.

239. While Barr and Seratec were finalizing negotiations, Celgene and Seratec entered into an exclusive supply agreement for thalidomide. Upon information and belief, Celgene demanded exclusivity from Seratec to interfere with Barr's ability to market generic Thalomid.

240. Inducing this exclusivity agreement was a nakedly anticompetitive action undertaken by Celgene to ultimately delay and exclude Barr from entering the market for Thalomid. First, Celgene had a separate API supplier that independently was filling its own API supply needs and had sufficient supply to meet projected growth requirements. Second, Seratec itself had sufficient resources to meet all of Celgene's needs without exhausting supply, leaving Seratec capable of supplying Barr, but for the exclusivity provision.

241. Due to Celgene's anticompetitive scheme, Seratec would not supply Barr with its thalidomide API. FDA did not accept Barr's ANDA due to deficiencies in providing a DMF from Seratec.[87]

242. Consequently, Barr was forced to find a different thalidomide supplier and repeat testing, causing it great expense and delay in launching generic thalidomide.

243. On February 27, 2006, Celgene's competitive intelligence firm, GBMC, updated Celgene that Barr completed BE testing and was planning on filing a thalidomide ANDA in the second quarter of 2006 using API from either Antibioticos of Italy or Shilpa of India. GBMC noted that "[t]hese companies were being used to replace the Seratec API that Barr originally was using for its ANDA."

[87] It was unclear to Celgene how Barr acquired Thalomid samples for BE testing in 2005. In Celgene's response to interrogatories in a separate litigation recently made public, Celgene noted "Celgene informed FDA of its belief that Barr had acquired Thalomid® capsules from a pharmacy in Astoria, New York in violation of the requirements of the S.T.E.P.S. program. FDA informed Celgene that it did not intend to 'recapture' these capsules from Barr, and that the manner in which Barr obtained Thalomid® for use in its bioequivalency testing would not affect FDA's consideration of any subsequent ANDA with respect to thalidomide that Barr might file."

244. After securing a new supplier and performing new BE studies and validation testing, Barr submitted its thalidomide ANDA on September 22, 2006. The ANDA showed that Barr's generic product was bioequivalent to Celgene's Thalomid. FDA accepted Barr's thalidomide ANDA for filing on December 4, 2006.

245. Celgene subsequently initiated a patent infringement lawsuit against Barr for its thalidomide ANDA, as discussed more thoroughly below, initiating an automatic 30-month stay of FDA's approval of Barr's ANDA.

246. GBMC predicted that Barr could be expected to receive FDA approval of its thalidomide ANDA in the first quarter of 2009.

247. In a May 2009 email between executives at Celgene, which contained the minutes of a previously held internal meeting, these executives discussed Barr's attempt to market generic thalidomide in the USA.[88]

248. According to the minutes of the meeting: "Dianne Azzarello Regulatory Canada discussed possible ways to defend Thalidomide against generic infiltration in the USA. From her experience in working with generic drug providers she is of the opinion that [Celgene was] able to use bioequivalence as generic defense strategy. The team supports this notion. If generic companies have to effectively prove that they are at least equivalent to what Celgene has to offer including Celgene's RiskMap before making product available on the market."

249. The meeting participants also discussed paying for research and publishing research papers stating generic manufacturers' version of Thalomid were not bioequivalent: "Diane Azzarello and Henry Lau are working with Dr. Iain McGilveray who will publish a paper providing evidence that many other formulations of thalidomide available are not bio equivalent

[88] Exhibit to MSJ Opp., Doc. No. 284-4.

to Celgene's Thalomid. We may also include our simple formulation and its chemical properties as rationale. Funding for this publication is estimated to be $40k $60k."

250. These internal discussions are further evidence Celgene was not negotiating the sale of sample drugs to generic manufacturers nor executing contracts with exclusivity provisions with suppliers in good faith, instead seeking to foreclose generic entry into the markets for Revlimid and Thalomid.

C. Celgene's Patents Ostensibly Protecting Revlimid are Subject to Strong Invalidity, Unenforceability, Non-infringement, and Improper Orange Book listing arguments.

251. Even when a generic manufacturer managed to obtain a sample of Thalomid or Revlimid, Celgene was still able to unlawfully block them from the market by obtaining and asserting invalid and improper patents. Celgene's patents were subject to strong invalidity and unenforceability arguments, including as to key patents on which Celgene relied to exclude generic competition, namely the '517 compound patent and the polymorph patents.

1. The '517 Compound Patent is Invalid as Obvious over the Prior Art.

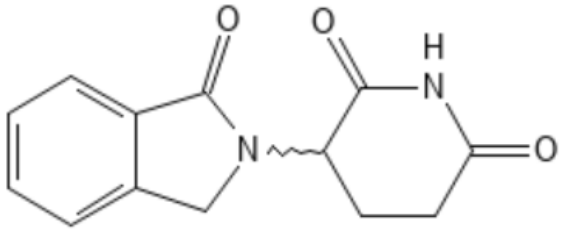
252. The original, core patent for the composition of Celgene's thalidomide-derived drugs is the '517 Patent, filed in 1996. It expired on October 4, 2019. Thalidomide, the drug on which Revlimid is based, was first marketed in 1957. The innovations on which the '517 Patent is based are obvious in light of the innovations and research conducted long before Celgene began its effort to bring Revlimid and Thalomid to market; thus, the '517 Patent and the subsequent patents derived from it are invalid.

253. A person working in the relevant field would have identified thalidomide and its analogs as effective in treating a variety of conditions, including the reduction of TNFα levels. It would have been a natural choice to select EM-12 and/or 4-aminothalidomide as lead compounds for further development efforts, due to their favorable properties and the promise

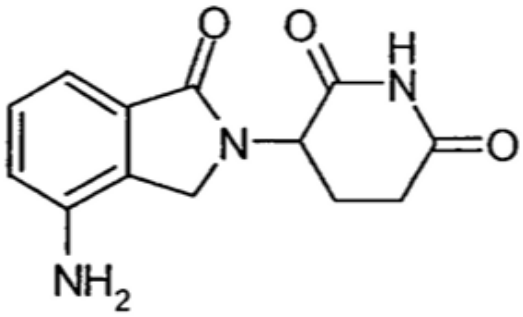
both compounds had shown. A small, conservative change to either one of two lead compounds, EM-12 or 4-aminothalidomide, would result in lenalidomide. The conservative changes that would need to be made to EM-12 or 4-aminothalidomide (*i.e.*, the addition of an amino group or the subtraction of an oxygen atom, respectively) would be motivated by a desire to improve stability and/or solubility. In making these small changes, one would have had a reasonable expectation of success in producing a compound with beneficial properties due in part to the close structural similarity of the lead compounds to the claimed compound.

254. EM-12 is structurally similar to lenalidomide, differing only in the presence of an amino group (NH_2) at the 4-position of the phthalimidine ring.

EM-12



Lenalidomide[89]

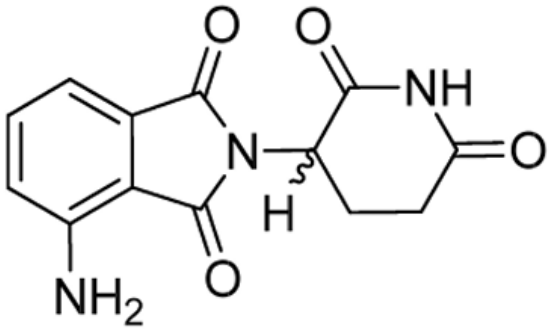


255. A person skilled in the art would be motivated to make the small structural change of adding an amino group to EM-12 at this particular location – a routine and easy change to make to the compound – as part of the standard steps in drug development and optimization.

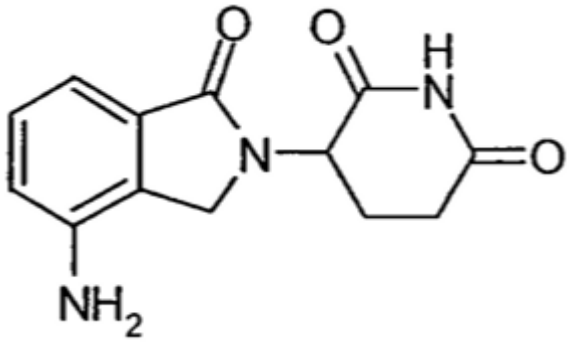
256. 4-aminothalidomide is structurally similar to lenalidomide, differing only in that lenalidomide has one fewer oxygen atoms than 4-aminothalidomide:

[89] *See* Revlimid labeling information submitted by Celgene to the FDA at p. 5, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021880s000_Revlimid_Prntlbl.pdf

4-aminothalidomide



Lenalidomide[90]



257. It has been well known in the scientific community for decades that thalidomide analogs have a tendency to undergo hydrolysis (*i.e.*, degradation in the presence of water) and therefore one skilled in the art would have been motivated to make the well-known modification of subtracting the oxygen atom from this location to reduce the chance of hydrolysis and thereby promote stability. Indeed, the subtraction of an oxygen atom from this location is how one would obtain EM-12 from thalidomide, with the resulting compound having a superior stability profile as compared to thalidomide.

258. Taking into account: the structural similarity of the lead compounds (EM-12 and 4-aminothalidomide) to lenalidomide; the teachings of the prior art regarding known modifications to improve the compound's chemical properties (*e.g.*, stability and solubility); the small, conservative changes at issue (*i.e.*, either the addition of an amino group or the subtraction of a single oxygen atom); and the totality of the prior art on thalidomide analogues (including EM-12 and 4-aminothalidomide specifically), a person skilled in the art would have been motivated to make the conservative changes at the specified locations with a reasonable

[90] *See* Revlimid labeling information submitted by Celgene to the FDA at p. 5, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021880s000_Revlimid_Prntlbl.pdf

expectation of success in creating a compound with beneficial properties. The '517 claim for the lenalidomide compound is obvious in light of the prior art and therefore invalid.

2. Celgene Misled the PTO During the Reexamination of the '517 Compound Patent, Rendering it Invalid and/or Unenforceable.

259. A review of the Re-examination of the '517 Patent during patent prosecution illustrates its invalidity and Celgene's unlawful methods of procuring patents while constructing its patent thicket.

260. The '517 has ten claims. Claims 1 – 9 claim methods-of-use as to six compounds. In contrast to these method of treatment claim, Claim 10 of the '517 claims four compounds, including lenalidomide. One of the method of treatment claims (Claim 8) pertains to pomalidomide. However, pomalidomide is not one of the compounds claimed in Claim 10 of the '517.

261. On April 14, 1998, Celgene filed a Request for Reexamination concerning the '517. Celgene "sought reexamination because of a question raised by a non-adversarial third party, a potential licensee, as to the significance of certain prior art." Celgene sought reexamination of claims 1-10 of the '517 patent "in view of (l) D'Amato, U.S Patent No. 5,593,990 issued Jan.14,1997; (2) D'Amato, U.S. Patent No. 5,629,327; (3) D'Amato, U.S. Patent No. 5,712,291 (together, "the D'Amato Patents"); (4) in view of Leibovich et al. U.S. Patent No. 4,808,402 and (5) Leibovich et al., Macrophage-lnduced Angiogenesis is Mediated By Tumor Necrosis Factor-α, Letters To Nature, Vol. 329, pages 630-632, pub. 15 October, 1987" (together, the "Leibovich References").

262. On November 11, 1998, the PTO granted the request for reexamination, explaining Celgene "is correct to allege that all three of the primary references, namely, the D'amato Patents possess the same disclosure and both of the ancillary reference, namely, the

Leibovich et al. Patent and Journal article possess essentially the same disclosure. [] The requester alleges that the three D'Amato patents generically teach[] the compounds of the involved patent under reexamination and that both Leibovich et al. references may be relevant because they teach the concept of Tumor Necrosis Factors possess[ing] the unexpected ability to induce angiogenesis, which is related to the involved patent under reexamination, albeit with different compounds, which appears to have relevance. **A substantial new question of patentability affecting claims 1-10 of United States Patent No. 5,635,517 is raised by the request for reexamination**."

263. On December 9, 1998, Celgene submitted its Statement as to why the newly disclosed prior art references did not render the '517 patent invalid for obviousness, arguing: "D'Amato clearly does not describe or suggest the compounds used in the claimed method defined by claims 1-9 or those recited in claim 10. Regardless of what compounds the D'Amato patents do disclose, however, those references cannot render obvious the claimed method of reducing TNFa levels. This is also true of Leibovich et al. and D'Amato in combination with Leibovich et al. The Patent Owner sought reexamination, not because it believed D'Amato was relevant, but because of a question raised as to the significance of D'Amato by a nonadversarial third party. While D'Amato may raise a substantial new question of patentability, and should be considered, it is submitted that the ultimate question of patentability must be resolved in the Patent Owner's favor with a finding confirming the patentability of claims 1-10. Favorable action is earnestly solicited."

264. On February 22, 1999, the PTO rejected all claims of the '517 as unpatentable over the three D'Amato patents (the '990, '327, ' and '291) and in view of the two Leibovich references, finding, "**there is ample information in the prior [art] to motivate one of**

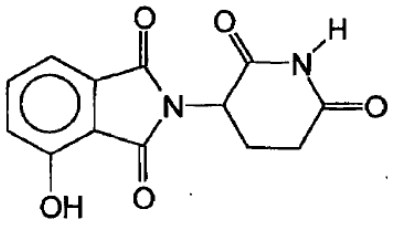
ordinary skill in the chemical arts to place [applicant's] compounds in possession of the public." Explaining its determination that the claims were unpatentable as obvious, the PTO stated:

> [T]he record has shown and the patentee has admitted in the record that the 3 D'Amato patents contain the same disclosure and said D'Amato patents supra disclose the very closely analogous compounds . . and methods for their preparation. . . . there is a teaching of equivalence between hydrogen, hydroxy, epoxy and amino as possible substituents on the 4,5,6 and 7 positions of the benzene ring of the said 1-oxo- or 1,3-dioxo-isoindoline ring. The concept of angiogenesis and administering said reference compounds to a patient with toxic concentrations of TNF-α is taught [in the D'Amato patents]. The [Leibovich references] represent an excellent reference for the known compound "thalidomide" which represents activation of macrophages, their relationship to angiogenic activity and a method of controlling abnormal concentrations of TNF-α factor associated with solid malignant tumors, benign tumors, leukemias and the like. . . . Since the properties of the prior art overlap with the ['517] under reexamination, and the 3-D'Amato patents teach the equivalents of hydrogen, hydroxy, epoxy and amino groups as substituents on each of the four positions on the benzene ring of the isoindoline nucleus, there is ample information in the prior [art] to motivate one of ordinary skill in the chemical arts to place applicants compounds in possession of the public.

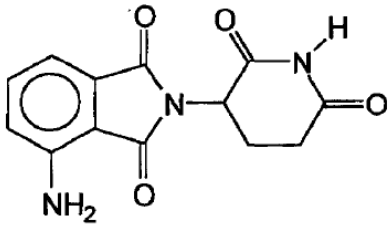
265. On February 25, 1999, Celgene submitted a Request for Reconsideration and attached a declaration from Dr. David I. Stirling, Celgene's then-Chief Scientific Officer and EVP (the "Stirling Declaration"). Celgene argued that any finding of obviousness was rebutted by the evidence of "unexpected properties" set forth in the Stirling Declaration.

266. The Stirling Declaration states in part: "Test were conducted under my supervision to evaluate the relative activities of test compounds to inhibit the levels of [TNF-alpha]. . . . These test were conducted on various compounds including the following:

Compound 1:



Compound 2:



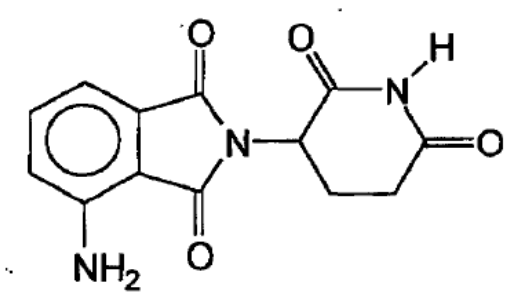
267. The Stirling Declaration further stated: "I conclude that Compound 2 is >10,000 fold more active than Compound 1 in this primary human cell-based assay."

268. In its accompanying Request for Reconsideration, Celgene explained Dr. Stirling's findings, stating: "As explained by Dr. Stirling, Compound 2 was >10,000 fold more active than Compound 1 in this assay. Compound 1 of course is the hydroxythalidomide compound of D'Amato; ***Compound 2 is the corresponding amino compound of the present claims***." Celgene concluded, "it is submitted that the D'Amato patents, alone or in combination with the Leibovich *et al.* patent and publication, do not establish a *prima facie* case of obviousness. If, however, these references are deemed sufficient to establish a *prima facie* case of obviousness, it is believed the same has been fully rebutted by the evidence of record demonstrating unexpected properties."

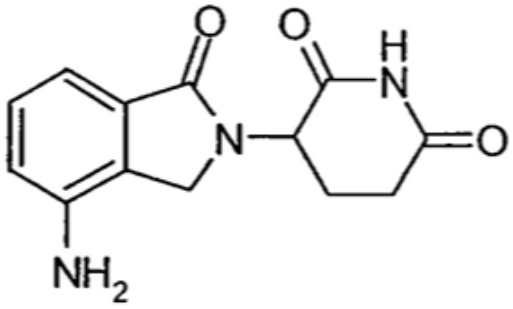
269. Shortly after Celgene's submission of the Request for Reconsideration and the Stirling Declaration, the PTO issued a Notice of Intent to Issue Reexamination Certificate allowing the claims of the '517.

270. However, "Compound 2" is not lenalidomide, nor is it any of the other compounds claimed by the '517. "Compound 2" is another thalidomide analogue, pomalidomide, which is not one of the compounds claimed by the '517 patent.

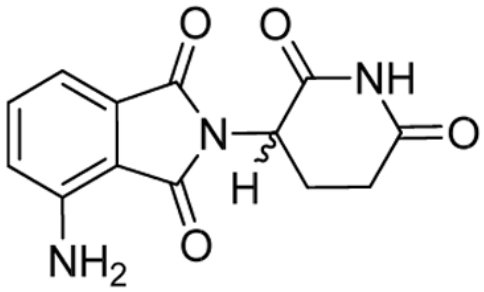
Compound 2:



Lenalidomide[91]



Pomalidomide[92]



271. As shown above, lenalidomide has one fewer oxygen atoms as compared to "Compound 2" referenced in the Stirling Declaration. The Stirling Declaration does not describe

[91] *See* Revlimid labeling information submitted by Celgene to the FDA at p. 5, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021880s000_Revlimid_Prntlbl.pdf

[92] *See* Pomalyst labeling information submitted by Celgene to the FDA at p. 10, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204026Orig1s000Lbl.pdf

testing of lenalidomide, or any of the other three compounds claimed by Claim 10 of the '517 patent.

272. "Compound 2" is in fact pomalidomide, which is mentioned in Claim 8 as part of a method of treatment claim, *i.e.,* "The method according to claim 7 in which said compound is 1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline." But the testing of "Compound 2" was irrelevant to the ***compound patent claims*** in Claim 10 of the '517. Celgene misled the PTO and breached its duty of candor by, *inter alia,* submitting testing that had nothing to do with the most vital part of the '517 patent, *i.e.,* the compound claims of Claim 10.

273. Also notable, Dr. Stirling states in his declaration that he performed testing on "various compounds." Yet, Dr. Stirling presented his findings with respect to only one comparator, *i.e.*., "Compound 1," which is a compound identified in the D'Amato patents. Celgene concealed the rest of the data; Celgene cherrypicked the results that would best support its claim of unexpected results.

274. In sum, the '517 is invalid. After Celgene submitted the D'Amato and Leibovich references to the PTO as part of the reexamination, the PTO rejected all claims of the '517 as invalid over the prior art. To overcome those obviousness rejections, Celgene submitted testing that purportedly showed unexpected results. However, the "unexpected results" did not pertain to any of the compounds claimed by the '517 patent. Celgene failed to overcome the PTO's finding of obviousness and the compound claims of the '517 are therefore invalid.

275. That Dr. Stirling intended to deceive the PTO is supported by the facts that (i) he had detailed first-hand knowledge of Celgene's thalidomide analogue testing program generally, including the testing that had been done as to lenalidomide and related analogues, as well as the results of that testing program, (ii) he did not submit all of the testing results relevant to the

issues raised during the ’517 examination, and (iii) he chose to present testing regarding a compound *other than* one of the compounds claimed by the ‘517 (i.e., other than the compounds that would have supported allowing reexamination) in support of patentability.

276. At minimum, under judicial scrutiny in litigation, the true facts would have rendered the ‘517 patent invalid. The same facts would also support a finding of inequitable conduct by David Stirling (who signed and submitted the declaration) and potentially Celgene’s in-house and outside counsel who submitted the Request for Reconsideration and supporting Stirling Declaration (Bruce M. Collins) and/or otherwise prosecuted the reexamination.

3. The PTAB’s Reasoning for Declining to Further Review of the ’517 Patent Contradicts the PTO’s Express Finding of Obviousness and Would Not Have Undermined Generics’ Strong Arguments Establishing Invalidity and/or Unenforceability.

277. On May 7, 2015, the Coalition for Affordable Drugs (the “Coalition”) filed a Petition for *Inter partes* Review (“IPR”) of Patent No. 5,635,517 (the “Coalition’s Petition”). The Coalition is an organization created by Hayman Capital Management, an asset management firm. To the extent a petition for inter partes review filed by the Coalition leads to fluctuations in a company’s stock price, Hayman Capital Management could benefit financially.

278. On November 16, 2015, the PTAB declined to institute review based on the Coalition’s Petition, which focused on five prior art references: Piper (1981); Kaplan (1995); Agrawal (1981); WO ‘085 (1994); and Keith (1992).

279. As discussed above in Section VII.C.i.2, in 1998 (less than a year after the ’517 initially issued), the ’517 underwent a reexamination by the PTO and was invalidated for obviousness. The PTO’s strong findings of invalidity were only overcome by Celgene’s submission of the highly misleading Stirling Declaration, which presented test results that had nothing to do with the compounds claimed by the ’517 patent. The PTAB did not address the

reexamination, nor did it address any of the prior art references on which the PTO based its findings of obviousness. The PTAB's conclusions are directly contradicted by the PTO's strong findings of invalidity.

280. With respect to the compound claims of the '517 (Claim 10), the PTAB concluded: "We likewise are not persuaded that an ordinary artisan would have had sufficient reason to prepare any of the four compounds recited in claim 10 [e.g., lenalidomide]. All four compounds in claim 10 comprise an amino group on the benzene ring (like AH 13 [4-aminothalidomide] and AH 14 [3-aminothalidomide]) and a single C=O in the 5-carbon ring (like EM 12). Petitioner has not established sufficiently, with reasonable underpinnings, why one would have produced such compounds for any reason, for example to produce analogs that inhibit angiogenesis (discussed in WO '085)."

281. The PTAB provides no support for this statement, which is directly contradicted by the findings of the PTO during the reexamination, which concluded: "The concept of angiogenesis and administering said reference compounds to a patient with toxic concentrations of TNF-α is taught [in the 5,593,990, 5,629,327, and 5,712,291 (the "D'Amato patents")]. The [Leibovich references] represent an excellent reference for the known compound "thalidomide" which represents activation of macrophages, their relationship to angiogenic activity and a method of controlling abnormal concentrations of TNF-α factor associated with solid malignant tumors, benign tumors, leukemias and the like. Thalidomide is the unsubstituted 1-oxo-2-(2,6-dioxopiperdin-3-yl) isoindoline respectively. Since the properties of the prior art overlap with the Muller et al. (U.S. Patent No. 5,635,517) under reexamination, and the 3-D'Amato patents teach the equivalents of hydrogen, hydroxy, epoxy and amino groups as substituents on each of the four positions on the benzene ring of the isoindoline nucleus, there is ample information in the

prior [art] to motivate one of ordinary skill in the chemical arts to place applicants [sic] compounds in possession of the public."

282. Celgene was only able to overcome the PTO's conclusive findings of obviousness by submitting the fraudulent Stirling Declaration. That declaration falsely stated that a compound claimed in the '517 patent was surprisingly at least 10,000 times more active than hydroxythalidomide when, in fact, the tested compound was not even one of the four compounds claimed in the compound claim in the '517 patent.[93]

283. More generally, the PTAB's sweeping statement, suggesting that there is no reason "why one would have produced such compounds" dismisses the very impetus behind the drug development enterprise, which is to take promising lead compounds, and make small, systematic changes resulting in compounds with beneficial properties. To suggest that no one working in the field would have been motivated to undertake further development efforts with respect to promising lead compounds like EM-12 and 4-aminothalidomide ignores what was actually occurring in the field and contradicts the Supreme Court's instruction that a person skilled in the art is "a person of ordinary creativity, not an automaton."

284. The PTAB appears to have decided the ultimate outcome (i.e., no review instituted) and then stated conclusory (and erroneous) findings to reach that result based on an unduly narrow view of the relevant evidence. It is unclear whether the PTAB was swayed by the identity of the Petitioner. (As noted, the Coalition is backed by a hedge fund that could benefit financially from fluctuations in Celgene's stock price.) What is clear is that the PTAB's findings

[93] *See supra* Section VII.C.i.2 (explaining that the Stirling Declaration presented testing data that compared the D'Amato compound (Stirling's "Compound 1") to pomalidomide (Stirling's "Compound 2"), which is not one of the four compounds claimed by the '517).

are directly contradicted by the PTO's findings of obviousness during the reexamination, which Celgene only overcame by submitting the false Stirling Declaration.

285. The PTAB proceedings do not alter the fact that the generic challenges to the validity of the '517 were highly likely to prevail.

4. Celgene's Unlisted Polymorph Patents Claiming Form A ('357, '219, '598 Patents) are Invalid as Anticipated and Celgene Itself Submits Evidence Suggesting the '517 is Not Enabled.

286. Celgene's filings in other proceedings, such as in the course of defending its polymorph patents in proceedings before the European Patent Office ("EPO") further indicate the invalidity of its polymorph patents.

287. Polymorphism refers the ability of a compound to form with different crystal structures. Although the different polymorphic forms of a compound will have the same chemical composition, the differences in crystalline structure impact the compound's chemical properties, such as solubility and bioavailability. Polymorphic forms are identified by their particular X-ray powder diffraction pattern, with peaks at specified locations. Celgene obtained several lenalidomide polymorph patents in the U.S. and in Europe.

288. On November 2, 2011, the EPO issued European Patent ("EP") 1,667,682, a lenalidomide polymorph patent. Claim 14 of EP '682 claims a polymorphic form having an X-ray powder diffraction pattern with peaks at approximately 8, 14.5, and 16 degrees 2θ. Celgene defines the lenalidomide polymorph with peaks at these locations as "Form A."

289. Celgene's U.S. polymorph patents, 7,977,357, 8,431,598, and 8,193,219, claim polymorphic forms with peaks in the same or similar locations:

EP '682, Claim 14	"Crystalline 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione, which has an **X-ray powder diffraction pattern comprising peaks at 8, 14.5 and 16 degrees 2θ**."

US '357, Claim 3	"An unsolvated crystalline Form A of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione of claim 1, which has **an X-ray powder diffraction pattern comprising peaks at approximately 8, 14.5, and 16 degrees 2θ**."
US '598, Claim 5	"A solid form of 3-(4-amino-1-oxo-1.3 dihydro-isoindol 2-yl)-piperidine-2,6-dione comprising an unsolvated crystalline form of 3-(4-amino-1-oxo-1.3 dihydro-isoindol-2-yl)-piperidine-2,6-dione having a differential scanning calorimetry thermogram endotherm at approximately 270° C. and an **X-ray powder diffraction pattern comprising peaks at approximately 8, 14.5, and 16 degrees 2θ** and a thermogravimetric analysis curve indicative of an unsolvated material, wherein the crystalline form is present at greater than about 80% by weight of the total weight of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione."
US '219, Claim 1	"A pharmaceutical composition for oral administration comprising between 5 mg and 25 mg of an unsolvated crystalline 3-(4-amino-1-oxo-1.3 dihydro-isoindol-2-yl)-piperidine-2,6-dione having **an X-ray powder diffraction pattern comprising peaks at approximately 8, 14.5, 16,** 17.5, 20.5, 24. and 26 degrees **2θ,** and a pharmaceutically acceptable excipient, diluent, or carrier, wherein the composition is a solid dosage form."

290. On January 8, 2012, Mylan filed a Notice of Opposition with the EPO requesting that the EPO revoke EP '682 as lacking novelty in light of (i.e., anticipated by) Celgene's (US) '517 Patent. Mylan asserted that, if the steps in Example 1 of the '517 are carried out, it results in the same polymorph claimed by Claim 14 of the EP '682: "The inevitable consequence of following the process described in prior art document [the '517 Patent] is the preparation of a crystalline form of lenalidomide having peaks corresponding to those peaks claimed in claim 14 [of EP '682]."

291. On February 8, 2012, Teva filed a Notice of Opposition similarly requesting the revocation of EP '682 on the basis of, *inter alia,* lack of novelty in light of the '517. As with Mylan, Teva's experts carried out Example 1 of the '517 and reported: "We have checked the [X-ray powder diffraction ("XRPD")] data obtained and compared it with the XRPD data

reported in EP 1 667 682. In my opinion there can be no doubt that the lenalidomide I obtained (both samples) is the same polymorph form as the polymorph for designed for A in EP 1 667 682."

292. On March 9, 2015, Celgene filed the declaration of Dr. Natarajan in an attempt to counter the testing results submitted by Mylan and Teva. Dr. Natarajan explained that he "was asked to synthesize . . . lenalidomide, by exactly following the procedures of . . . Example 1 of U.S. Patent No. 5,635,517." Rather than providing support for Celgene's argument that its polymorph patents are not anticipated, Celgene's own expert actually presented results that cast further doubt on the validity of the '517. In his sworn declaration, Dr. Natarajan reported that he did not obtain lenalidomide (polymorph or otherwise) ***at all***: "No lenalidomide was formed in the hydrogenation reaction . . . ." In other words, the data presented by Celgene's expert supports the argument that the '517 lacks enablement and is therefore invalid.

293. On June 24, 2015, the EPO issued a decision revoking EP '682 based on the rationale that Form A claimed by EP '682 was anticipated by the '517 patent. In so holding, the EPO remarked on Celgene's failure to present evidence to suggest that the '517 does not inevitably lead to Form A, noting that Celgene instead asserted that it was unable to obtain lenalidomide at all when following the '517:

> The opposition division is of the opinion that also in the present case the best way of countering the experimental report of Prof. Dr. Kirschning would have been to present own results [sic], which demonstrate that the process as disclosed in Example 1 of . . . [the '517] does not inevitably lead to the form A in question. If the proprietor would have presented such results, the argumentation of the opponents would have lost a lot of its credibility. However the proprietor did not make use of this option and instad [sic] ***merely demonstrated that the compound*** 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione ***(lenalidomide) could not be obtained at all when the procedure of Example 1 was exactly followed in the repetition of the experiment***.

294. For the same reasons that EP '682 is invalid, so too are the '357, '598, and '219, all of which also claim Form A. Mylan and Teva's uncontroverted testing showed that, when

Example 1 of the ’517 is carried out, Form A lenalidomide inevitably results. Thus the ’357, ’598, and ’219 are invalid as anticipated by the ’517.

295. If the only patents Celgene had protecting lenalidomide were these three polymorph patents (’357, ’219, ’598 Patents) – which Celgene did *not* list in the Orange Book as claiming lenalidomide – Celgene would have had no standing to bring paragraph IV Hatch Waxman litigation against an allegedly infringing generic, so could not have triggered the FDA’s 30-month stay of ANDA approval or provided a pretextual lawsuit for purpose of negotiating an (anticompetitive) settlement before generic entry and/or robust generic competition.

5. Celgene’s Listed Polymorph patents (the ‘217 and ‘800 patents) are Also Subject to Invalidity and Non-Infringement Challenges.

296. To extend its monopoly on the sale of thalidomide derivatives, Celgene began filing additional patent applications seeking to claim other polymorphic forms of lenalidomide. Polymorphs, also known as solvates or crystalline forms, of previously patented compounds are routinely developed as a standard practice in the pharmaceutical industry, according to a US patent examiner in a rejection of one of Celgene’s polymorph patent applications, and generally not separately patentable.

297. Nonetheless, Celgene managed to get the USPTO to approve its polymorph patents and list them in the Orange Book. These patents—the ’800 Patent and the ’217 Patent—expire in 2027 and 2024, respectively. Since these patents have the latest expiration dates of any patents associated with Thalomid or Revlimid, they have been key patents cited in repeated attempts by Celgene and Bristol-Myers Squibb to block generic competitors from the market. Celgene routinely cites these polymorph patents against generic manufacturers that have filed generic Revlimid and/or Thalomid ANDAs.

298. In doing so, Celgene and Bristol-Myers Squibb have also repeatedly exposed the polymorph patents to charges of invalidity and have repeatedly settled instead of testing the strength of these patents in court for fear of the result. When Natco Pharma Limited ("Natco Pharma") filed an ANDA for its generic version of lenalidomide, Celgene brought suit against it, Watson, and Arrow International Ltd., ("Arrow") (collectively, "Natco") claiming infringement.[94] The parties agreed to a *Markman* hearing to settle the meaning of disputed patent terms. Citing Celgene's own clarified definition of the term "hemihydrate," Natco amended its invalidity contentions to the '800 Patent, arguing that it was invalid for indefiniteness, lack of enablement, and lack of written description. When Celgene was unable to prevent Natco from raising these amended invalidity contentions, Celgene quickly settled with Natco with an anticompetitive reverse payment settlement agreement, described more fully *infra* Section VII.E. Having learned a dangerous lesson, Celgene did what was necessary to avoid a similar *Markman* hearing over the meaning of "crystalline" in its subsequent litigation against Dr. Reddy's and other generic manufacturers.[95]

299. Celgene knows that the overbroad terms of its redundant polymorph patents are an attempt to block generic competitors from bringing non-infringing products to market where the generic manufacturer has developed a suitable workaround to Celgene's patents. The claims of Celgene's other polymorph patent, the '217 Patent, also call out crystalline and hemihydrate forms, and are invalid for the same reasons as the '800 Patent. Celgene has entered into

[94] *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197, 2015 WL 4138982 (D.N.J. Jul. 9, 2015). Celgene alleged that while Natco Pharma filed the ANDA, Arrow assisted Natco Pharma in preparing and filing the ANDA, and Watson prosecuted the ANDA before FDA.

[95] Letter to Court, *Celgene Corp. v. Dr. Reddy's Laboratories Ltd.*, 2:16-cv-7704 (D.N.J. Mar. 23, 2018), ECF No. 77. On the date that its responsive *Markman* pleadings were due, Celgene filed a letter informing the court that it resolved its claim construction disputes with Dr. Reddy's and would not be filing responsive pleadings.

stipulations dismissing the ’217 Patent and/or executing a covenant not to sue on the ’217 Patent in actions against eight separate generic manufacturers.[96] By doing this, Celgene shields the ’217 Patent, and the patents derived therefrom, from judicial scrutiny and invalidation. Nonetheless, Celgene continues to sue generic rivals on the ’217 Patent solely to delay generic entry.

300. These patents, like the ’517 Patent from which they were derived, were obtained due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent. Celgene’s failure provides an independent basis for invalidity. These polymorphs are also obvious variants of the composition of matter patent, adding a further basis for invalidity. Finally, based on Celgene’s own representations in the *Markman* hearing that was held in the *Natco* litigation, the claims of the patent are unenforceable as overbroad.

6. The Federal Circuit held Celgene’s key REMS patents (including the ’501, ’720) invalid; Celgene stopped asserting the rest (’976, ’977, and ’784 Patents).

301. As discussed above, in 1998, Celgene only listed the ’501 Patent in the Orange Book in connection with Thalomid. Since then, it has listed numerous additional patents, including the ’720, ’976, ’977, and ’784 Patents (together with the ’501 Patent, the “REMS patents”) in the Orange Book as covering Thalomid.

[96] *See* Statement, *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197, ECF No. 140 (D.N.J. Aug. 31, 2012); Statement, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842, ECF No. 81 (D.N.J. Aug. 8, 2018); Statement, *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:17-cv-02528, ECF No. 93 (D.N.J. Aug. 8, 2018); Stipulation and Order of Dismissal, *Celgene Corp. v. Cipla Ltd*., No. 2:17-cv-06163, ECF No. 63 (D.N.J. Aug. 16, 2018); Statement, *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al*., No. 2:18-cv-11630, ECF No. 50 (D.N.J. Jan. 22, 2019); Consent Judgment, *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461, ECF No. 63 (D.N.J. Apr. 30, 2019); Stipulation and Order of Dismissal, *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2:18-cv-17463, ECF No. 54 (D.N.J Jan. 21, 2020); Statement, *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:20-cv-00003, ECF No. 120 (N.D. W. Va. Oct. 9, 2020).

302. The '501 and '720 patents were invalidated by the Patent Trial and Appeal Board ("PTAB") on October 26, 2016.[97] The same logic dictates that Celgene's other REMS patents are also invalid. Celgene stopped pressing its other REMS patents in litigation against generics after the Federal Circuit affirmed the PTAB decision.

303. The PTAB found the '501 Patent invalid as obvious over the combined disclosures of three asserted prior art references as representative of the level of ordinary skill in the art.

304. Guidance regarding the clinical use and dispensing of thalidomide was provided by an existing publication in 1994 that identified a patient subpopulation of women who could and wished to become pregnant, warning that they should not be treated with Thalomid, and recommending counseling on the risks of thalidomide as well as the use of contraception.[98]

305. Further guidance was also provided by the existing pregnancy-prevention program for women users of Accutane, a Vitamin A analogue of isotretinoin and a known teratogenic drug. Accutane was subject to a program of preventative measures, such as pregnancy-risk warnings on packaging, targeting of women of childbearing age for the pregnancy-prevention program, and communication between physicians and patients regarding the drug's teratogenic risk and the need to prevent pregnancy.[99]

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[97] See *Coalition for Affordable Drugs VI LLC, et al., v. Celgene Corp.*, IPR2015-01092, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01092; IPR2015-01096, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01096; IPR2015-01102, Paper No. 75 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01102; IPR2015-01103, Paper No. 76 (Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01103 ("*Coalition*").

[98] R.J. Powell and J.M.M Gardner–Medwin, *Guideline for the clinical use and dispensing of thalidomide*, POSTGRAD MED. J. 79, 901–904 (1994) ("Powell").

[99] Allen A. Mitchell et al., *A Pregnancy–Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, NEW ENG. J. MED. 333:2, 101–06 (Jul. 13, 1995) ("Mitchell").

306. Guidance for the use of a national database to register prescribers, pharmacies, and patients as a way to restrict access to drugs that could be potentially hazardous was also published well before the '501 Patent was filed, such as the nationwide registry for patients requiring clozapine, a potent anti-psychotic drug with potential for serious side effects.[100]

307. The PTAB found that a person of ordinary skill in the art would have understood how to implement Powell's teachings in clinical and pharmacy settings in view of the Accutane Pregnancy Prevention Program and the Clozaril (clozapine) controlled distribution model outlined in Dishman. The PTAB was not persuaded by Celgene's argument that the prior art did not specifically single out men who could impregnate a woman as a subgroup, noting that a skilled artisan would have recognized that the sperm of male patients could be damaged by teratogenic drugs and consequently result in birth defects if the male was to impregnate a female.[101]

308. The PTAB found the '720 Patent invalid as obvious over the combined disclosures cited against the '501 Patent for the original S.T.E.P.S. program, while finding that the inherent dangers of Thalidomide would drive someone of ordinary skill in the art to proactively improve the system. Citing U.S. Patent No. 5,832,449 (issued Nov. 3, 1998, "Cunningham"), which describes an approval code used by prescribers and pharmacies to track and manage pharmaceutical products, the PTAB found that a person of ordinary skill in the art could predict that such an approval code could be utilized by prescribers and pharmacies to track and manage Thalomid and Revlimid. In light of this prior art, the PTAB invalidated the '720 Patent as obvious.

[100] Benjamin R. Dishman, et al., *Pharmacists' role in clozapine therapy at a Veterans Affairs medical center,* AM. J. HOSP. PHARM. 51, 899–901 (Apr. 1, 1994) ("Dishman").

[101] *Coalition,* IPR2015–01092, Paper No. 73.

309. As the PTAB noted, "[w]hen it benefitted [Celgene's] interests before FDA, [Celgene] freely admitted that its 'plan [for thalidomide] is built on experience with restrictions on such other drugs with severe adverse effects as Accutane … and Clozaril."[102] Before the USPTO however, Celgene repeatedly failed to disclose the very materials that it relied on in presenting its program to FDA, along with other similar prior art such as the Clozaril Patient Monitoring Service and numerous published works describing the features of REMS programs similar to Celgene's original and modified S.T.E.P.S. programs.

310. On July 30, 2019, the Federal Circuit affirmed the findings of the PTAB invalidating the '501 and '720 patents for obviousness.[103]

311. The '976 Patent, the '977 Patent, and the '784 Patent, filed more than three years later, are nearly identical to the invalidated '501 and '720 patents. In fact, many of these patents were so similar that Celgene did not even bother changing the title or abstract describing the patent.[104]

312. As explained above, at least the '720, '977, '784, and '399 patents are unenforceable due to inequitable conduct because the applicants of these patents, including Williams, as well as their agents, attorneys and/or others substantively involved in the prosecution of those patents, concealed from the PTO prior art references that they knew were

[102] IPR2015-01092, at 24 (P.T.A.B. Oct. 26, 2016).

[103] *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019).

[104] At least the '720, '977, '784, and '399 patents are also unenforceable due to inequitable conduct because the applicants of these patents, including Zeldis's co-inventor Williams, as well as their agents, attorneys and/or others substantively involved in the prosecution of those patents, concealed from the PTO prior art references that they knew were material to patentability—including the CPMS, Honigfeld I, Honigfeld II, the Guide, the PPP, the PPP Package, the CDC Meeting and Transcript, the CDER Meeting (including Williams' presentation) and Transcript, and/or the NIH Meeting (including Williams' presentation) and Transcript—with intent to deceive the patent examiner. As a patent related to and directed to an invention not sufficiently distinct from the unenforceable '720, '977, '784, and '399 patents, the '018, '566, '886 and '531 patents are likewise unenforceable under the doctrine of infectious unenforceability (an argument raised by generics in litigation). In particular, each of the '018, '566, and '531 patents is terminally disclaimed over the '720, '977, '784, and/or '399 patents, and the '866 patent is terminally disclaimed over the '566 patent.

material to patentability—the CPMS, Honigfeld I, Honigfeld II, the Guide, the PPP, the PPP Package, the CDC Meeting and Transcript, the CDER Meeting (including Williams' presentation) and Transcript, and/or the NIH Meeting (including Williams' presentation) and Transcript—with intent to deceive the patent examiner.

313. As a patent related to and directed to an invention not sufficiently distinct from the unenforceable '720, '977, '784, and '399 patents, the '018, '566, '886 and '531 patents are likewise unenforceable under the doctrine of infectious unenforceability. In particular, each of the '018, '566, and '531 patents is terminally disclaimed over the '720, '977, '784, and/or '399 patents, and the '866 patent is terminally disclaimed over the '566 patent.

7. Celgene's Method of Treatment Patents are Not a Roadblock for Generic Entry.

a. Celgene's '740 MDS method of treatment patent is subject to strong invalidity and unenforceability challenges, including as to the date of conception of the invention

314. The patent prosecution of the '740 Patent shows how Celgene engaged in deceitful tactics to obtain invalid method of use patents that should not have issued and would have been invalidated at trial but for Celgene's monopolistic scheme, including its practice of settling all its sham litigations to shield its patents from judicial scrutiny.

315. Celgene's method of treatment patent 7,189,740 is a continuation of U.S. Application No. 10/411,649 filed Apr. 11, 2003. Application No. 10/411,649 stems from Provisional Patent Application No. 60/418,468 filed on October 15, 2002. Based on this information, one would understand the priority date for the '740 to be October 15, 2002.

316. During the prosecution of what led to the '740 patent, the PTO rejected the claims as anticipated over U.S. Application No. 03/0235909 and U.S. Application No. 04/0067953

("Stein"). The PTO also rejected the claims as anticipated or obvious over WO 01/87307 and for double patenting over U.S. Application No. 10/438213.

317. To overcome the PTO's rejection, Celgene filed a declaration by Jerome Zeldis, Celgene's then-Vice President and Chief Medical Officer, dated August 17, 2005 (the "First Zeldis Declaration"). The First Zeldis Declaration states: "**I conceived of the presently claimed invention in the '649 application prior to March 8, 2002**, the date of the first filed application to which Stein claims priority. This is evidenced by a clinical trial protocol identified within Celgene as 'MDS-501-001' which is entitled "A PHASE II OPEN LABEL STUDY OF THE SAFETY AND EFFICACY OF CC-5013 (REVIMID®) TREATMENT FOR PATIENTS WITH MYELODYSPLASTIC SYNDROME.' A redacted copy of the front page of this protocol description is attached hereto as Exhibit D."

318. The First Zeldis Declaration continues, "Specifically, the protocol for treating MDS with REVLIMID® was designed based upon my conception, and under my supervision and direction, prior to March 8, 2002. Patients were enrolled and treated with REVLIMID® under the protocol from prior to March 8, 2002 to the filing date of the present application. This is evidenced, in part, by the abstract attached hereto as Exhibit E, List et al., 'High Erythropoietic Remitting Activity of the Immunomodulatory Thalidomide Analog, CC-5013, In Patients with Myelodysplastic Syndrome (MDS),' American Society of Hematology Abstract #353, 2002, which reports the results obtained under the protocol MDS-501-001. This study is also disclosed in Section 5.3. 'Clinical Studies In MDS Patients,' on pages 34-35 of the specification."

319. Contrary to Dr. Zeldis's assertion, none of the cited references support his claim that he "conceived of the claimed invention prior to March 8, 2002." Exhibit D is a single page from the protocol, from which all date information has been conspicuously omitted:

A PHASE II OPEN LABEL STUDY OF THE SAFETY AND EFFICACY OF CC-5013 (REVIMID™) TREATMENT FOR PATIENTS WITH MYELODYSPLASTIC SYNDROME

PROTOCOL MDS-501-001

FINAL PROTOCOL DATE:

ORIGINAL PROTOCOL DATED:

Principal Investigator:	_____ Signature of Investigator: By my signature, I agree to personally supervise the conduct of this study and to ensure its conduct in compliance with the protocol, informed consent, IRB/EC procedures, instructions from Celgene representatives, the Declaration of Helsinki, ICH Good Clinical Practices guidelines, and the applicable parts of the Code of Federal Regulations governing the conduct of studies. Alan F. List, M.D. Section of Hematology /Oncology Arizona Cancer Center University of Arizona Tucson, AZ 85724 Telephone: (520)626 2340 Facsimile: (520) 626 2415
Sponsor:	Celgene Corporation 7 Powder Horn Drive Warren, New Jersey 07059 Telephone: (732) 271-1001
Medical Monitor:	Robert Knight, M.D. Celgene Corporation 7 Powder Horn Drive Warren, NJ 07059 Telephone: (732) 805-3749 Facsimile: (732) 805-3623

320. Similarly, Exhibit E is an abstract from the December 6-10, 2002 annual meeting of the American Society of Hematology that describes a study, but provides no information about the date of the study. The same is true for the referenced pages of the specification.

321. Subsequently, the PTO rejected the claims, *inter alia*, as obvious over a newly-cited prior art reference, Raza (August 2001, Blood), in view of WO 01/87307 (international publication date of November 22, 2001). In response, Celgene submitted a second declaration from Dr. Zeldis dated June 22, 2006 (the "Second Zeldis Declaration.")[105] In *this* declaration, Dr. Zeldis claims, "**I conceived of treating MDS with Revlimid before July 19, 2001**."[106] He cites the same Exhibits D and E and the same section of the specification. However, no exhibits are attached the Second Zeldis Declaration; and as noted above, the referenced pages of the specification do not provide any date information. Shortly after the submission of the Section Zeldis Declaration, the '740 Patent issued (subject to terminal disclaimer as to U.S. Patent Application No. 10/438,213).[107]

322. The '740 Patent is invalid. The PTO found that the claimed invention was obvious over the prior art, including Raza (August 2001) in view of WO '307. Dr. Zeldis submitted no documentation that supports his assertion that he had "conceived of the claimed invention prior to March 8, 2002" (the First Zeldis Declaration") nor does he submit any evidence to support his later claim that he had "conceived of treating MDS with Revlimid before July 19, 2001." Celgene therefore failed to overcome the PTO's findings of obviousness.

b. A Significant Portion of Celgene's Method of Treatment Patents were Subject to Section viii Carve Outs by Generic Manufacturers.

[105] Patent file wrapper PDF at p. 794-796.
[106] *Id.* (emphasis added).
[107] Terminal disclaimer dated June 23, 2006 (patent file wrapper PDF at p. 792).

323. While Celgene improperly obtained *sixteen* method of treatment patents, many of these related to uses that were susceptible to section viii carveouts.[108] Through a section viii carveout, a generic can limit the number of patents at issue in litigation by seeking ANDA approval on one or more of the FDA approved indication, and omit from its label information about other approved indications. Often a generic company includes in its label the original approved indication and omits additional indications that are claimed by patents with later expiration dates. The FDA and Congress encourage generic companies to use Section viii carve outs in order to bring generic drugs to market as soon as possible.

324. From the three Final and Temporary Approval letters that are publicly available, it is apparent that generics were contemplating and/or employing this strategy.

325. The following lists the publicly available methods-of-use patents that have been carved out by each generic manufacturer.

Generic	Section viii Carve Outs
Lotus	’363 patent, ’406 patent, ‘929 patent, ‘730 patent, ‘238 patent
DRL	’363 patent, ‘406 patent, ‘929 patent, ‘730 patent, ‘238 patent
Natco	’363 (it appears), ’406 patent, ’730 patent, ’238 patent, ’621 patent

326. For instance, Natco’s Final Approval Letter confirms that it certified section viii carveouts for the '406, '621, '730, and '238 patents. Additionally, from the redacted text it appears that Natco may have been contemplating a carveout for less common uses of the ’363 Patent, including for treatment of MCL, follicular cancer, and marginal zone lymphona.

[108] *See* 21 U.S.C. § 355(j)(2)(A)(viii).

327. While all of Celgene's methods-of-use patents are invalid, generic manufacturers would have only needed to address subsections of these patents to prevail at trial and bring a competing generic to market.

c. Celgene's Multiple Myeloma Method of Treatment Patents are Obvious Over the Prior Art

328. Celgene's multiple myeloma method of treatment patents (the 7,968,569, 8,530,498, 8,648,095, and 9,101,622) claim the administration of lenalidomide in combination with dexamethasone in specific dosing regimens. The initial non-provisional applications for these method of treatment patents claimed the benefit of a May 17, 2002 provisional application (Application No. 60/380,842) and a November 6, 2002 provisional application (Application No. 60/424,600).

329. The multiple myeloma method of treatment patents are subject to strong invalidity challenges, including obviousness. It was well known in the prior art before May 17, 2002 that lenalidomide in combination with steroids such as dexamethasone was used to treat cancers. To overcome the PTO's rejections for obviousness, Celgene submitted findings it argued showed that it had determined, before the date of its May 2002 application, that there were unexpected results in the administration of lenalidomide in combination with dexamethasone in specific dosing regimens. However, Celgene's unexpected results either were not, in fact, unexpected or post-date the claimed invention by a significant period of time. For example, during the prosecution of the '569 patent Celgene stated that it "submitted numerous publications which support that the claimed combination therapy showed surprising, unexpected and synergistic effects for treating multiple myeloma patients." In support of this statement, Celgene cited the following references:

> . . . . Weber et al., Abstract #412, American Society of Hematology, December 8-11, 2007; Harousseau et al., Abstract

#3598, American Society of Hematology, December 8-11, 2007; Foa et al., Abstract #4839, American Society of Hematology, December 8-1,. 2007; Chanan-Khan et al., Abstract #2721, American Society of Hematology, December 8-11, 2007; Wang et al., Abstract #P0-662, XI International Myeloma Workshop and IV International Workshop on Waldenstrom 's Macroglobulinemia #3553, American Society of Hematology, December 9-12, 2006. Also see the publications submitted on February 26, 2007, Rajkumar et al., Blood, Dec. 15, 2005, l06 (13)4050-4053; WEBER et al., Abstract# PO. 7 38, International Multiple Myeloma Workshop, April 10-14. 2005; RICHARDSON et al., Blood, Abstract# 825, American Society of Hematology, Dec. 6-9, 2003; WEBER, Abstract# Pl5.02. International Multiple Myeloma Workshop, April 10-14, 2005; CELGENE CORPORATION Press Release, February 2003; RICHARDSON et al., Best Practice & Research Clinical Haematology, 2005, 18 (4):619-634; HUSSEIN et al., Blood, Abstract #208, American Society of Hematology, Dec. 4-7, 2004; and BAZ et al., "Blood, Abstract# 2559, American Society of Hematology, December 10-13, 2005.

330. However, the publications noted above all post-date the claimed invention, often by years; none of these showed that at the time Celgene claimed it has made the invention that it has shown there to be unexpected results. The citations did not support a finding of patentability. The generic manufacturers had strong invalidity challenges to the multiple myeloma method of treatments patents (several of which are subject to terminal disclaimers) and would have entered the market earlier, either by successfully invalidating the patents or by negotiating an earlier entry date, under competitive conditions.

D. Celgene Filed Baseless Citizen Petitions to Stymie Generic Approval

331. As part of its multifaceted and decades long scheme to monopolize the market for Thalomid and Revlimid, Celgene filed baseless citizen petitions against generic manufacturers when manufacturers belatedly managed to secure the necessary API to file an ANDA. Celgene engaged in such anticompetitive conduct to take advantage of its knowledge that it is the standard practice for FDA to withhold ANDA approval until FDA completes its research into

and response to a citizen petition. The filing of baseless citizen petitions occurred often in tangent with, and as a complement to, Celgene's sham patent litigations. *See infra,* Part VII.E.

332. To illustrate, Celgene filed a citizen petition concerning Barr's ANDA application on September 20, 2007, urging FDA not to approve Barr's thalidomide ANDA. Celgene submitted this citizen petition one year after Barr had filed its ANDA with FDA for generic Thalomid and nine months after Celgene had filed a sham patent litigation. Celgene's citizen petition was baseless and intended to delay Barr's entry into the market for generic thalidomide.

333. At a meeting with Celgene in 2012, FDA's Jane Axelrad, Associate Director for Policy at CDER, commented "since 2007, Celgene's citizen's petition states there are safety concerns and this is because the company does not want generics on the market."[109] In its citizen petition, Celgene requested that FDA withhold approval of any generic thalidomide product, or alternatively: i) require the application for generic thalidomide to be subject to the same conditions of approval applied to Thalomid under Subpart H of 21 C.F.R. Part 314; and ii) prohibit the restricted distribution program for the generic thalidomide product from authorizing prescriptions for, and registering patients with, multiple myeloma, in violation of Celgene's orphan drug exclusivity, which would expire in 2013.

334. Celgene's petition was meritless. It lacked any reasonable regulatory, scientific, medical, or other basis. FDA lacked statutory authority to withhold approval of generic thalidomide on the bases given by Celgene or to require the actions Celgene requested. Like its litigation against Barr, this citizen's petition was also a sham designed to maintain Celgene's monopoly.

[109] Exhibit to MSJ Opp., Doc. No. 285-15.

335. On December 19, 2008, Barr responded to the petition, arguing that it "is nothing more than yet another attempt by a brand company to block all generic competition using market exclusivity protecting just a single approved indication."[110] Barr explained that Celgene's pretextual safety concerns were "hyperbole designed to improperly play on the public's fears regarding thalidomide," and that Barr's proposed thalidomide would be safe and its label would contain all precautionary information contained in the Thalomid label. Specifically, Barr argued that the law permits it to carve-out from its label Thalomid's protected MM indication, and that "Barr's Thalidomide Labeling Need Not Contain The Multiple Myeloma Indication To Ensure The Safe And Effective Use Of The ANDA Product."

336. Nearly six years later, on September 30, 2014, FDA denied Celgene's citizen petition. Specifically, FDA "den[ies] your request that FDA decline to approve any ANDA for thalidomide."

337. Celgene's filing of baseless citizen petitions was part of, and advanced, its scheme to unlawfully monopolize the markets for Revlimid and Thalomid. As detailed above, Celgene used its baseless citizen petition to argue for a stay in Lannett's antitrust lawsuit against Celgene over its refusal to sell Lannett samples, further delaying Lannett's ability to file an ANDA and enter the market.

E. Celgene and Bristol-Myers Squibb Serially Commenced "Sham" Patent Litigation Before Inducing a Pay-for-Delay Settlement Agreement with Natco and Agreements with Later-Filing Generics that Shored Up the Anticompetitive Terms of the Natco Agreement

338. Celgene fraudulently obtained invalid patents in order to construct a patent thicket that would, along with the other anticompetitive tactics in its multi-faceted monopolistic scheme, prevent and delay generic competition. With its fraudulently obtained and invalid patents in

[110] Exhibit to MSJ Opp., Doc. No. 285-17.

hand, Celgene and BMS then serially filed "sham" patent litigations against would-be competitors. Due to Celgene's policy and practice of refusing to provide samples to would-be generic rivals, the details of many of which are outlined above, each generic manufacturer below had already been delayed by Celgene's multifaceted scheme and would have filed a Paragraph IV certification earlier. Knowing its patents were invalid and that asserting them would trigger the 30-month stay of FDA ANDA approval, Celgene asserted them solely for the purpose of continuing to delay generic competition as part of its multifaceted monopolistic scheme.

339. Then, after utilizing the 30-month stay to delay generic entry, Celgene induced generic companies to settle. Celgene induced an anticompetitive reverse payment settlement agreement regarding Revlimid with (1) the first-filers, Natco, Arrow, and Watson. Celgene then, leveraging its settlement with Natco, induced settlement agreements with numerous later-filing generics regarding Revlimid that shored up the anticompetitive terms in the Celgene-Natco agreement, including: (2) Alvogen and Lotus, (3) Dr. Reddy's, (4) Cipla, (5) Apotex, (6) Zydus, (7) Sun, (8) Hetero, (9) Mylan, (10) Aurobindo, (11) Torrent, (12) Biocon, (13) Lupin, and (14) Hikma (collectively, "Later-Filing Generics").

340. To date, after fifteen years of litigation comprising at least twenty-eight separate actions, Celgene and BMS have not allowed a single patent to face judicial scrutiny and judgment after trial by a District Court. Only a single remaining patent litigation, against Alembic, remains pending. There remains no generic Thalomid alternative on the market and there will be no true generic competition on Revlimid until 2026.

341. Celgene and BMS shielded its Revlimid and Thalomid patents by settling patent litigation before judicial scrutiny of its patents and sharing their monopoly rents by allocating a

portion of the market to each generic competitor in exchange for abandoning their patent challenges.

342. Celgene initiated a sham patent litigation against the first filer for Revlimid, Natco, before inducing it to delay its generic launch in exchange for a large, unjustified payment. This unlawful "reverse payment" comprised a two-pronged in-kind payment: (1) a volume limited, royalty-free generic license before full generic competition began, equating to hundreds of millions of dollars in payment to Natco; and (2) MFE clauses that both deterred later-filing generics from challenging Celgene's patents through judgment and induced Natco to accept a later entry date by eliminating the risk that Natco loses its lucrative exclusivity period.

343. Celgene also filed sham patent litigations and induced settlements against the Later-Filing Generic rivals. Celgene modeled these settlements on and designed them to complement the Natco settlement, further allocating the market for Revlimid and delaying generic entry.

344. In 2008, Celgene filed a patent infringement lawsuit against Barr, in 2015 against Lannett Holdings, Inc. and Lannett Company, Inc. (collectively, "Lannett"), and in 2018 against Hikma Pharmaceuticals International Ltd. and Hikma Pharmaceuticals USA, Inc. (collectively, "Hikma) for its thalidomide ANDAs.

345. In 2010, Celgene filed a patent lawsuit against Natco for its lenalidomide ANDA. In 2016, Celgene filed a patent lawsuit against Dr. Reddy's for its lenalidomide ANDA. In 2017, Celgene filed patent lawsuits against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, "Zydus"), Cipla Ltd. ("Cipla"), Lotus Pharmaceutical Co., Ltd. and Alvogen Pine Brook, LLC (collectively, "Alvogen"), and again against Dr. Reddy's for their lenalidomide ANDAs. In 2018, Celgene filed patent lawsuits against Apotex Inc. ("Apotex"), Hetero Labs

Ltd., Hetero Labs Ltd. Unit-V, Hetero Drugs Ltd., and Hetero USA, Inc. (collectively, "Hetero"), twice against Sun Global FZE, Sun Pharma Global Inc., Sun Pharmaceuticals Industries, Inc., and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"), again against Alvogen, Dr. Reddy's, Cipla, and Zydus for its lenalidomide ANDAs. In 2019, Celgene filed patent lawsuits against Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (collectively, "Mylan"), and again against Cipla, Hetero, and twice against Apotex. In 2020, Celgene filed patent lawsuits against Lupin Ltd. ("Lupin"), and again against Mylan and Hetero. In 2021, Celgene filed patent lawsuits against Hikma Pharmaceuticals USA, Inc. ("Hikma"), Aurobindo Pharma Ltd., Eugia Pharma Specialties Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo"), Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent"), Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. (collectively, "Biocon"), Lupin Ltd., and Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively, "Alembic").

346. In all cases, Celgene complained that the generic versions of Thalomid and/or Revlimid infringed Celgene's patents. In all cases, each generic defendant counterclaimed, alleging that Celgene's patents are invalid as prior art or for obviousness, or for lack of written description, under 35 U.S.C. §§ 101, 102, 103 and/or 112, and general principles of patent law, and/or noninfringed. Because Celgene knew that its patents were invalid, it also must have known that the litigation to enforce the invalid patents would be unsuccessful. It brought the actions only because the filing would delay generic entry.

347. As detailed above, Revlimid and Thalomid were the key assets acquired by Bristol-Myers Squibb in its acquisition of Celgene on November 20, 2019. On information and belief, including but not limited to the importance of Revlimid and Thalomid to the success of

the acquisition and the extensive due diligence performed by Bristol-Myers Squibb in the course of evaluating the merger, Bristol-Myers Squibb directed, oversaw, and/or ratified the monopolistic scheme described in this Complaint. Thus, all actions described herein, including the anticompetitive reverse payment agreement and complementary agreements described here, are equally attributable to Bristol-Myers Squibb, particularly as to all agreements following the merger, described below, for which Celgene is the sole executing Bristol-Myers Squibb entity.

1. Celgene Initiates Patent Infringement Litigation Against Revlimid First-Filer Natco.

348. On August 30, 2010, Natco sent a Paragraph IV certification letter to Celgene, which contained a detailed factual and legal statement as to why Revlimid REMS patents, as well as the ’517, ’230, ’554, ’106, and ’800 patents are invalid, unenforceable, and/or not infringed by Natco’s proposed generic Revlimid.[111]

349. Shortly after, in September of 2010, Natco filed ANDA No. 201-452 seeking approval to bring lenalidomide capsules to market (in 5mg, 10mg, 15mg, and 25mg strength).

350. On October 8, 2010, Celgene filed a patent infringement suit against Natco in the District of New Jersey.[112]

351. Celgene continued to pursue new patents for its Revlimid product. In 2012, it listed two new patents in the Orange Book in connection with the formulation of Revlimid (patent no. 8,288,415) and another REMS patent (patent no. 8,315,886). In response, Natco sent Celgene an additional Paragraph IV certification on March 14, 2013 which contained a detailed factual and legal statement as to why the ’415 and ’866 patent are invalid, unenforceable, and/or not infringed by Natco’s generic Revlimid product.

[111] Answer and Counterclaims to First Amended Complaint, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. Jan. 14, 2010).

[112] Complaint, *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197 (D.N.J. Oct. 8, 2010).

352. On April 10, 2013, Celgene caused patent no. 8,404,717 to be listed in the Orange Book for Revlimid. The '717 patent is a method of use patent for the treatment of myelodysplastic syndromes using lenalidomide.[113]

353. Celgene filed a Fifth Amended Complaint against Natco on May 6, 2013.[114] Celgene alleged that Natco's generic Revlimid product would infringe the Revlimid REMS patents, as well as the '886 patent, the '517, '230, '554, '106, '800, '415, '717 and '598 patents. Natco denied these allegations and argued that the '517, '230, '554, '106, '800, '415, '717 and '598 patents are invalid and that its proposed generic lenolidamide product did not infringe Celgene's '800 patent as it does not contain lenalidomide hemihydrate. The invalidity of these patents is discussed above. Natco also filed counterclaims against Celgene, alleging fraud on the USPTO, and invalid and/or unenforceable patents.

354. Meanwhile, Celgene had abandoned its efforts to assert many of its ill-gotten and invalid patents. On January 20, 2011, Celgene informed the court that it covenanted not to sue Natco on the '326 Patent and '432 Patent.[115] On August 31, 2012, Celgene did the same for the '217 Patent, which, along with the '800 Patent, is one of Celgene's two key polymorph patents.[116] And on September 26, 2012, Celgene again covenanted not to sue Natco on the '763 Patent.[117] In exchange, Natco dropped its counterclaims of invalidity against Celgene.

[113] Later that month, Celgene was issued another patent (patent no. 8,431,598). Celgene did not cause this patent to be listed in the Orange Book, but did allege infringement against Natco and other later filers.

[114] Amended Complaint (Fifth), *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197, ECF No. 215 (D.N.J. May 6, 2013).

[115] Statement, *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197, ECF No. 24 (D.N.J. Jan. 20, 2011).

[116] *Id.* at ECF No. 140 (D.N.J. Aug. 31, 2012).

[117] *Id.* at ECF No. 145 (D.N.J. Sep. 26, 2012). In its Answer, Natco provided twenty-six pages of prior art references that render the '763 Patent invalid and/or unenforceable. 2:12-cv-04571, ECF No. 15, Exh. B (D.N.J. Sep. 28, 2012).

355. A *Markman* hearing was held on May 15, 2014. On May 27, 2014, the Hon. Susan D. Wigenton issued a *Markman* Opinion resolving disputed claim definitions in Natco's favor on three of the five disputed terms at issue.[118] These included narrowing constructions regarding the '554, '230, '357, and '598 patents, likely indicating that Natco would have prevailed under a noninfringement theory as to these pharmaceutical patents ('554 and '230 Patents) and polymorph patents ('357, and '598 Patents). Indeed, following the Opinion, Celgene stipulated to the dismissal of the '554 and '230 patents, as below.

356. Natco's strategy also included an attack on the '800 and '217 Patents, two polymorph patents that expire in 2027 and 2024, respectively.[119] As above, these patents are invalid for obviousness. Nonetheless, Natco also alleged that it had invented around these patents. The polymorph patents, including the '357 and '598 Patents, claim multiple different polymorph embodiments of lenalidomide, which are labeled "Form A", "Form B", all the way through "Form H". The different polymorph embodiments differ based upon their levels of solvation or hydration. For instance, Form A is "unsolvated" and Form B is "hemihydrated". They also differ based upon specific testing results (such as X-Ray powder diffraction) that serve as "finger prints" or identifying characteristics of each different polymorph.

357. Celgene attempted to argue that these embodiments were not claimed, specific polymorphs, but merely exemplars. In arguing for this (rejected) construction, Celgene's counsel inadvertently revealed just how difficult it would be for Celgene to prove infringement by listing the numerous specifications that an ANDA would need to have: "This is what they're talking about reading in. So I don't know how you would put the chart in there, but you'd have to put

[118] *Markman* Opinion, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 6, 2013), ECF No. 312.
[119] As above, Celgene covenanted not to sue on the (earlier expiring) '217 patent.

words to it. And they'd have another one, and another one, and another one, and another one, and another one, and another one, and another one, and another one, and it's just keeps going. This is all the material they are suggesting should be read into this claim, this term, to define Form A. My finger is getting tired, but I'm almost done. This is what is the claim would look like with - and it's not even all of it because we couldn't fit it on one slide."[120] In other words, unless Natco (or another generic's) product had *each* of the innumerable characteristics, it would not infringe.

358. The Court rejected Celgene's attempt, limiting "Form A to mean a particular polymorph with these distinguishing characteristics." This cleared the way for Natco to prevail on noninfringement where it's ANDA did not exhibit *each and every* characteristic specified in the exact polymorph forms disclosed – an unlikely proposition as demonstrated by Celgene's *Markman* hearing arguments.

359. Additionally, the '800 Patent included the disputed term "hemihydrate." Natco argued that the term required an exact water to compound ratio of 0.5 to 1, and would have further limited the claimed polymorphic crystal form to what is called "Form B." Celgene, by contrast, argued that "hemihydrate", as used in the patent, implied an *approximate*, rather than exact, ratio. Under either construction, however, Natco's accused products *do not infringe* because they are an "anhydrous" form, i.e., a *form that has no water* in the crystal.

360. In the Court's *Markman* Opinion, the Court adopted Celgene's proposed definition, reading "hemihydrate," as a term of approximation.[121] Nevertheless, Celgene could only prove infringement of Natco's anhydrous product by arguing that *at some point* (such as after ingestion) Natco's product *would become* hemihydrated and infringe, an unlikely prospect.

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[120] Transcript, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 20, 2014), ECF No. 310, at 84.

[121] *Markman* Opinion, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 27, 2014), ECF No. 312, at 6-7. (finding that hemihydrate means "a hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate").

However, by arguing for this broader definition of hemihydrate to help its weak and speculative infringement argument, Celgene exposed the '800 Patent to new invalidity defenses.

361. Less than a month after the *Markman* hearing, Natco moved to amend its defenses to assert these defenses, arguing invalidity for indefiniteness, lack of written description, and lack of enablement.[122] With the gloss of the term of "approximately" applied to "hemihydrate", (1) a person of ordinary skill would be unable to determine the scope of the patent, (2) the patent did not disclose or suggest to a person of ordinary skill in the art that any hemihydrate form of lenalidomide other than Form B even exists, let alone clearly convey that the patentee was in possession of other hemihydrated forms of lenalidomide, and (3) the patent does not disclose how to make a hemihydrated form, other than Form B, having the claimed characteristics.[123]

362. Celgene vigorously fought Natco's motion, opposing amendment in a July 11, 2014 opposition brief.[124] And when Magistrate Judge Arleo granted Natco's motion,[125] Celgene immediately appealed the Opinion and Order, likely because it would have ultimately required Celgene to answer for the invalidity issues its own claim construction had created. Briefing over the granted amendment extended into January 2015 before Judge Wigenton.

363. Meanwhile, Celgene stipulated to dismissing its claims and defenses as to the '230 and '554 patents (following the Court's adoption of Natco's proposed claim terms regarding these patents), as well as the '106 and '415 Patents.[126]

364. On July 9, 2015, Judge Wigenton affirmed Magistrate Judge Arleo's Opinion and Order granting Natco's motion to amend its defenses to assert the new contentions opened up by

[122] Letter, 2:10-cv-05197, ECF No. 321 (D.N.J. June 19, 2014).
[123] *Id.* at 3.
[124] Letter, 2:10-cv-05197, ECF No. 331 (D.N.J. July 11, 2014).
[125] Opinion, 2:10-cv-05197, ECF No. 366 (D.N.J. Nov. 18, 2014).
[126] Stipulation of Dismissal, 2:10-cv-05197, ECF No. 402 (D.N.J. March 26, 2015).

the court's *Markman* Opinion.[127] The parties served expert reports in late summer 2015 and responsive expert reports in September 2015.[128] Shortly thereafter, some six years after litigation began, Celgene settled the patent litigation, shielding its patents from scrutiny before the court could address the infringement or invalidity of any of its patents.

2. Celgene Settles Patent Litigation with Natco/Arrow/Watson with an Anticompetitive Reverse Payment Agreement.

365. On December 22, 2015, Celgene announced the settlement of litigation with Natco Pharma Ltd. of India, Natco's U.S. partner, Arrow International Limited, and Arrow's parent company, Watson Laboratories, Inc. (a wholly owned subsidiary of Allergan plc) (for these purposes, collectively "Natco") relating to patents for REVLIMID® (lenalidomide).[129]

366. At this time there was a substantial probability that Natco's lenolidamide product would be adjudged non-infringing, Celgene's patents would be invalidated, and/or Natco would launch its Revlimid generic "at risk." To avert devastation to its falsely constructed monopoly over lenolidamide products, Celgene bought off its would-be competitor, Natco.

367. By the express and implied economic terms of the agreement—some but not all of which are set forth explicitly in the settlement documentation—the agreement contained an anticompetitive reverse payment from Celgene to Natco. For its part, Celgene shared profits by allocating a volume-limited small number of generic sales to Natco beginning in March 2022. In exchange, Natco agreed to delay entry of its generic version of Revlimid until 2026 (eleven years later).

[127] Opinion, 2:10-cv-05197, ECF No. 440 (D.N.J. July 9, 2015).

[128] *See* Amended Scheduling Order, *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 6, 2013), ECF No. 449.

[129] Press Release, Celgene Corp., Celgene Settles REVLIMID® Patent Litigation (Dec. 22, 2015), http://ir.celgene.com/releasedetail.cfm?ReleaseID=947998.

368. By both the terms and effect of the arrangement, Celgene agreed to share its monopoly rents with Natco as a *quid pro quo* for Natco's agreement not to compete with Celgene until January 31, 2026. Celgene shared profits by allocating a volume-limited number of generic sales to Natco beginning in March 2022.

369. On December 22, 2015, Celgene announced:

> In settlement of all outstanding claims in the litigation, Celgene will permit entry of generic lenalidomide before the April 2027 expiration of Celgene's last-to-expire patent listed in the Orange Book for REVLIMID®. Celgene has agreed to provide Natco with a license to Celgene's patents required to manufacture and sell an unlimited quantity of generic lenalidomide in the United States beginning on January 31, 2026. In addition, Natco will receive a volume-limited license to sell generic lenalidomide in the United States commencing in March 2022. The volume limit is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry. The volume limitation is expected to increase gradually each 12 months until March of 2025, and is not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license under this agreement.[130]

370. Celgene and Natco kept the details of the payment terms secret from the Court, the public, and Plaintiff.

371. On a February 12, 2016 earnings call, Natco further disclosed that the license referred to by Celgene in its announcement was royalty free. Natco also newly disclosed the inclusion of an acceleration clause, allowing for earlier Natco entry triggered by other generic market entries.[131]

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[130] Press Release, *Celgene Settles REVLIMID Patent Litigation*, dated December 22, 2015, available at https://www.businesswire.com/news/home/20151222005986/en/ (last accessed March 29, 2022).

[131] *See* Natco Pharma Q3 FY 2016 Earnings Conference Call" February 12, 2016, *available at* https://natcopharma.co.in/wp-content/uploads/2016/02/NirmalBang-NatcoPharma-Feb12-2016.pdf ("… if something triggers a launch date earlier than 2022 so the agreement has standard accelerated clauses with respect to everything, so if such an event were to happen so it is 22 limited quantity which will increase over a period of time to unlimited quality till 26 or in the event that something happens to the patents or certain events which are defined in our agreement, there are whole slew of events that are defined, standard accelerated clauses kick in which allows us an earlier entry as well.").

372. Individually and collectively, these payment terms are anticompetitive. First, the volume-limited royalty-free license allocates the market by eliminating the incentive to compete on price (i.e., to increase volume), ensuring that prices will remain at supra-competitive levels even after generic entry. As Teva (Natco's marketing partner) described, Celgene set up a "profit share."[132] The royalty-free generic license prior to true generic competition constitutes a large reverse payment from Celgene to the generic that equates to hundreds of millions of dollars in the first year of generic sales alone. Second, the acceleration clause deters other generics from continuing to challenge Celgene's patents, and provides assurance to Natco that it will receive the most favorable entry date and retain its lucrative exclusivity period.

373. Natco executives celebrated the supracompetitive profits it planned to make from the Revlimid settlement to investors:

> Revlimid looks like a blockbuster. If you look at the guidance that they have given they have given ***very obscene numbers on how big the brand will be***, right now it is about 3.5 billion. I have seen projections in the US and globally I think it is doing 5, 6 billion, they are saying it will be a $8, $9 billion brand so I think it will stay and I am still very positive about it . . . .[133]

374. The settlement caused Natco to delay its *bona fide* full market entry until January 31, 2026.

375. On December 23, 2015 (the day on which the Revlimid settlement was announced) Celgene's stock price leaped upward by 9.8%, confirming the additional monopoly profits Celgene would gain from delayed competition. Stock prices reflect investors' expectations about a company's future profits. A dramatic upward change in the stock price reflects an upward revision in profit expectations. Generally, an increase in the brand's stock

[132] *See* "Q1 FY 2019 Teva Pharmaceutical Industries Ltd. Earnings Conference Call" May 2, 2019, *available at* https://www.fool.com/earnings/call-transcripts/2019/05/02/teva-pharmaceutical-industries-limited-teva-q1-201.aspx.

[133] *Id.* at 20.

price after a patent litigation settlement indicates that the settlement delayed generic entry beyond investors' expectations.[134]

376. Celgene's stock price increase equates to a staggering increase in market capitalization of **$8.6 billion**, the single largest percentage increase in Celgene's stock price in 2015. Trends in the overall market do not explain the spike as the S&P 500 increased by only 1.2% on the same day. Natco's stock price went up too, increasing 2.3% on the Bombay Stock Exchange upon announcement of the settlement.[135] Without an alternative explanation, investors interpretation of the settlement as benefiting both Celgene and Natco indicates that joint profits were increased by delaying genuine generic competition.

3. Celgene Initiates and Settles Sham Litigation against At Least Four Other Generics, Shoring up the Anticompetitive Terms of its Agreement with Natco.

377. Celgene settled at least four later patent infringement suits against generic companies on terms that served to shore up the anticompetitive terms (and the attendant windfall of profits) of the reverse payment Natco agreement. As explained further below, virtually all of the terms of the later generic settlements have been concealed from Plaintiff and the public. None of the later filed generics entered the market before the March 2022 date agreed to in Natco's. Celgene's actions in settling these other ANDA litigations served to preserve the ill-gotten gains and market allocation with Natco, by, in part, ensuring that generics accepted Natco's March 2022 entry date (and did not try to leapfrog over Natco to enter earlier with their own product) and forestalling robust generic competition until at least January 31, 2026.

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[134] See Drake, Starr, and McGuire, Do "Reverse Payment" Settlements Constitute an Anticompetitive Pay-for-Delay?" *International Journal of the Economics of Business*, 22(2), 2015, pp. 173-200and McGuire *et al.*, "Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements," *Iowa Law Review*, 101, 2016, pp. 1581-1599.

[135] http://www.myiris.com/newsCentre/storyShow.php?fileR=20151223130747199&secTitle=activestock&arttype=news.

a. Celgene Settles with Dr. Reddy's.

378. As part of its unlawful anticompetitive strategy, Celgene filed three serial patent infringement suits against Dr. Reddy's for the sole purpose of delaying generic entry into the lenalidomide market. Although Dr. Reddy's obtained Final Approval on October 14, 2021, it still has not launched a generic Revlimid. But for Celgene's anticompetitive scheme, Dr. Reddy's would have gained temporary and final approval far earlier and launched a competing generic Revlimid.

379. First, on September 9, 2016, generic manufacturer Dr. Reddy's sent Celgene a Paragraph IV certification notifying Celgene that it had filed ANDA No. 209-348 with the FDA seeking approval to market generic Revlimid. On October 10, 2016, Celgene sued Dr. Reddy's in the District of New Jersey.[136] Celgene later sued Dr. Reddy's in two additional suits alleging infringement of Celgene's later-acquired patents.[137] Dr. Reddy's answered, in all three litigations, that the patents asserted were not duly or lawfully issued.[138]

380. The parties filed a Joint Claim Construction Hearing and Statement on October 26, 2017, in which Dr. Reddy's notified the court that "the construction of the claim term 'crystalline' will be 'most significant to the resolution of the case' and 'will be case or claim dispositive or substantially conducive to promoting settlement,' at least with respect to the '800 and '217 patents on crystalline lenalidomide."[139] Although the '800 and '217 patents are invalid for obviousness, Dr. Reddy's had nonetheless invented around these keys patents (set to expire in 2024 and 2027) and its ANDA did not infringe Celgene's patents.

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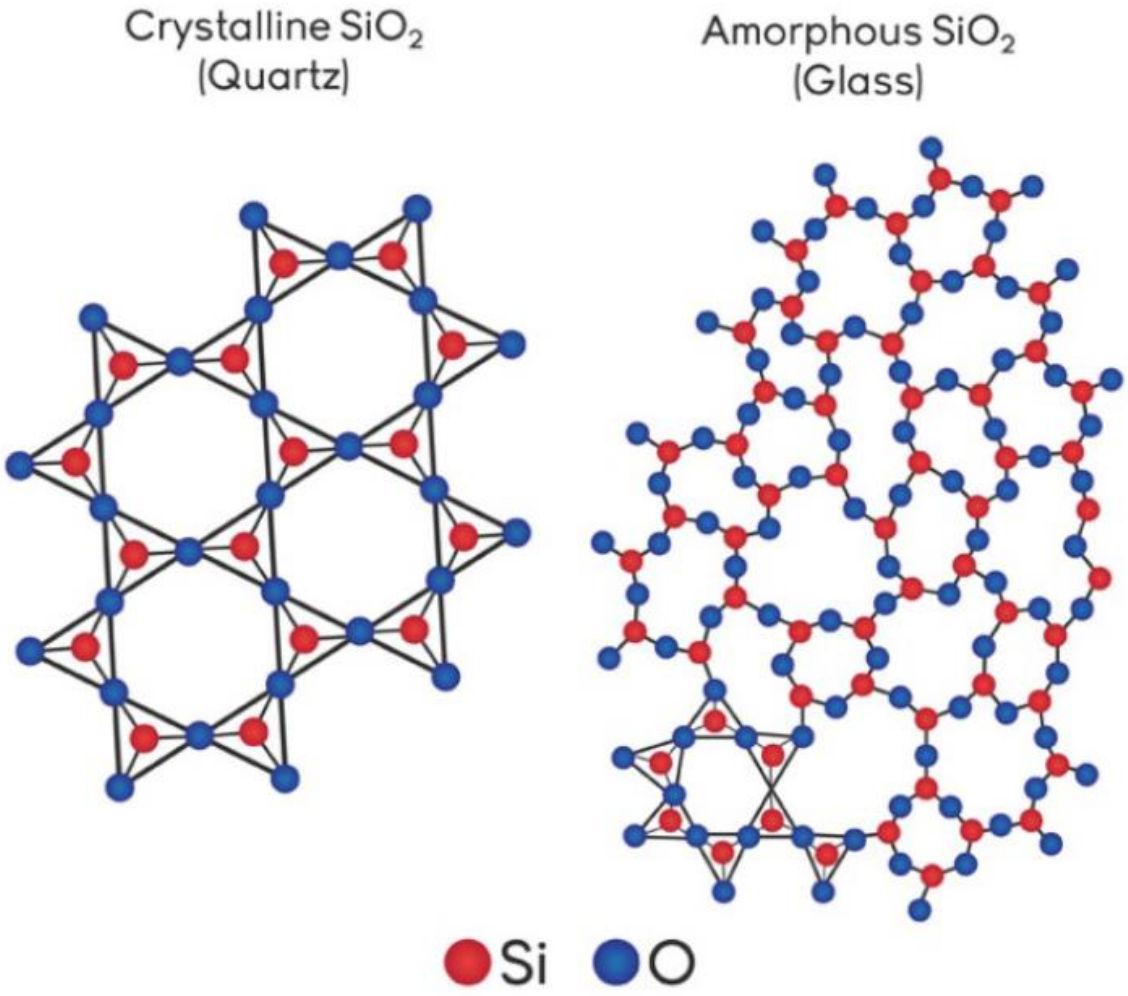
[136] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:16-cv-07704 (D.N.J).

[137] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, 2:17-cv-05314 (D.N.J.); and *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, 2:18-cv-06378 (D.N.J.).

[138] *See* No. 2:16-cv-07704, ECF No. 7 (D.N.J. Nov. 18, 2016); 2:17-cv-05314, ECF No. 17 (D.N.J. Oct. 18, 2017); 2:18-cv-06378, ECF No. 30 (D.N.J. May 31, 2018).

[139] No. 2:16-cv-07704, ECF No. 57, at 4-5 (D.N.J. Oct. 26, 2017).

381. As detailed in its *Markman* brief, while Celgene's Polymorph patents claim a "crystalline lenalidomide," Dr. Reddy's ANDA product comprises an "*amorphous* lenalidomide" structure. With the support of "the intrinsic and extrinsic record, as well as the understanding of the person of skill in the art" amorphous structures "are not crystalline," but rather "composed of randomly oriented molecules with no long-range order."[140]



382. This distinction, likely establishing noninfringement, was further highlighted by the prosecution history of the patents. Celgene had initially attempted to include claims covering

[140] No. 2:16-cv-07704, ECF No. 67, at 1, 4 (D.N.J. Dec. 22, 2017)

amorphous as well as crystalline forms, but, following rejection by the examiner, Celgene cancelled and removed the amorphous claims from the application.[141]

383. Celgene initially opposed Dr. Reddy's proposed construction. However, following briefing, on March 23, 2018, Celgene notified the court that the parties had resolved their claim construction disputes and would not be filing responsive *Markman* briefs.

384. On information and belief, Celgene had conceded to Dr. Reddy's construction of "crystalline", paving the way for Dr. Reddy's to argue its ANDA did not infringe Celgene's key Polymorph patents because were Celgene to oppose it (as in the *Natco* litigation), it would have opened its patents up to strong invalidity arguments.

385. Dr. Reddy's had also previewed winning invalidity arguments regarding Celgene's method of treatment patents (for myelodysplastic syndromes) in PTAB proceedings, showing Celgene that Dr. Reddy's had a clear path to market on at least a skinny label. Celgene's '740, '717, and '120 patents were anticipated by invalidating prior art, including press releases from years earlier. Dr. Reddy's introduced the two press releases bearing dates which would have invalidated the patent. In response, Celgene *did not deny* that the press releases were in fact published on the relevant dates, but instead disingenuously argued that the date on the press release did not *themselves* establish that their press release was published. While the PTAB was forced to deny institution on this technicality, Dr. Reddy's—and Celgene—knew that Dr. Reddy's could easily remedy this evidentiary technicality during District Court proceedings and invalidate Celgene's method of use patents.

[141] ECF No. 67, at 4-5 (D.N.J. Dec. 22, 2017).

386. On September 17, 2020, Celgene[142] announced a settlement of its litigation with Dr. Reddy's.[143] Similar to Celgene's agreement with Natco, Celgene's announcement provided only minimal details of the deal between Celgene and Dr. Reddy's. As stated in their press release:

> Celgene has agreed to provide DRL with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the U.S. beginning some time after the March 2022 volume-limited license date that Celgene previously provided to Natco. The specific volume-limited license date and percentages agreed-upon with DRL were not disclosed and are confidential. In addition, Celgene has agreed to provide DRL with a license to Celgene's patents required to manufacture and sell an unlimited quantity of generic lenalidomide in the U.S. beginning no earlier than January 31, 2026.

387. The settlement agreement between Dr. Reddy's and Celgene served to shore up the anticompetitive reverse payment deal. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Dr. Reddy's. The volume-limited small caps ensure that Dr. Reddy's has no incentive to compete on price (because, as with Natco, a price reduction does not increase output).[144] As in the case of the settlement with Natco, Celgene has no incentive to launch an AG. The net result of the agreement is that there will be no price competition, and Celgene retains its ability for a longer period to sell brand Revlimid at a monopoly pricing. The agreement with Dr. Reddy's solidified, and was in part induced by, Celgene's earlier agreement with Natco.

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[142] Bristol-Myers Squibb acquired Celgene in November of 2019, for clarity, this complaint will continue to refer to the brand defendant as Celgene. As above, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Dr. Reddy's.

[143] Brisol Myers Squibb Announces Settlement of U.S. Patent Litigation for Revlimid (lenalidomide) with Dr. Reddy's, *Available at,* https://www.businesswire.com/news/home/20200917005211/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-With-Dr.-Reddy%E2%80%99s.

[144] While Dr. Reddy's qualified for first-filer statutory exclusivity for two of the six formulations – the 2.5mg and 20mg capsules – neither Dr. Reddy's nor Natco have an incentive to compete on price.

388. Plaintiff is forced to purchase brand-name Revlimid at Celgene's supracompetitive prices until true price competition is expected to start, in 2026.

b. Celgene Settles with Lotus (Alvogen).

389. As part of its unlawful anticompetitive strategy, Celgene filed two serial patent infringement suits against Lotus and Alvogen, Inc. (collectively, "Lotus"). It brought the actions only because the filing would delay generic entry into the lenalidomide market. Although Lotus obtained Temporary Approval on September 24, 2020, it still has not launched a generic Revlimid. But for Celgene's anticompetitive scheme, Lotus would have gained temporary and final approval far earlier and launched a competing product.

390. On September 6, 2017, Celgene filed a patent infringement action against Lotus for filing ANDA No. 210480 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '517 Patent, '720 Patent, '977 Patent, '784 Patent, '740 Patent, '800 Patent, '217 Patent, '569 Patent, '886 Patent, '717 Patent, '498 Patent, '531 Patent, '095 Patent, '120 Patent, '621 Patent, and the '622 Patent.[145]

391. On July 10, 2018, Celgene filed another patent infringement action against Lotus, alleging Lotus's ANDA would also infringe its '357 Patent, '219 Patent, and the '598 Patent.[146] The patents that Celgene has claimed would be infringed in this case, however, have not been submitted to the Orange Book by Celgene in association with Revlimid as required pursuant to 21 U.S.C. §355(b)(1) and attendant FDA regulations. Celgene was required to list with its NDA, or within thirty days for a new patent after the NDA has been submitted, any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its drug. By citing these patents that were not filed in the Orange Book,

[145] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842 (D.N.J.).
[146] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al*, No. 2:18-cv-11518 (D.N.J.).

Celgene is either filing a frivolous infringement claim for a patent that it does not believe could be reasonably asserted or failing to list patents properly, which could give rise to administrative action or potentially additional antitrust liability if done in an attempt to delay filing and further extend its monopoly.

392. Lotus filed answers and counterclaims in all actions, alleging that all Celgene's asserted patents are invalid, unenforceable, or uninfringed.

393. On August 8, 2018, Celgene filed a Statement informing the court of its covenant not to sue Lotus for infringement of the '217 Patent.[147]

394. On December 17, 2018, the parties submitted a Joint Claim Construction Statement. As argued by Lotus, the methods-of-use patents for multiple myeloma (the '498 patent, '095 patent, '621 patent, and '622 patent) are invalid for, amongst other reasons, indefiniteness of key terms which the parties agreed to address through expert discovery.

395. Invalidation and/or a favorable construction regarding these methods-of-use patents, which expire on May 23, 2023, would have paved the way for a Lotus and/or other generic rivals to launch a "skinny-label" generic Revlimid for treatment of multiple myeloma, endangering Celgene's monopoly.

396. On February 22, 2019, Celgene and Lotus stipulated to bifurcating and staying all proceedings related to the REMS patents (the '720, '977, '784, '886, and '531 Patents), pending Celgene's appeal to the Federal Circuit of the PTAB's invalidation of the '720 Patent (ultimately affirmed on July 30, 2019).

397. On March 29, 2019, Celgene and Lotus announced a settlement agreement. The terms of the agreement are confidential, but Celgene and Lotus announced some details in a

[147] Statement, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842, ECF No. 81 (D.N.J. Aug. 8, 2018).

press release that is identical to that released in the Dr. Reddy's settlement,[148] indicating a similar settlement with another Later-Filing Generic protecting sales at monopoly pricing.

398. The settlement agreement between Lotus and Celgene also served to shore up the anticompetitive reverse payment deal and complementary agreement. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Lotus. The volume-limited small caps ensure that Lotus has no incentive to compete on price (because, as with Natco, a price reduction does not increase output). As in the cases of the settlements with Natco and Dr. Reddy's, Celgene has no incentive to launch an AG. The net result of the agreement is that there will be no price competition, and Celgene retains its ability for a longer period to sell brand Revlimid at a monopoly pricing. The agreement with Lotus solidified, and was in part induced by, Celgene's agreements with Natco and Dr. Reddy's.

399. The anticompetitive effects of Celgene's conduct are to again delay and forestall price competition in the lenalidomide market.

c. Celgene Settles with Cipla.

400. As part of its unlawful anticompetitive strategy, Celgene filed four serial patent infringement suits against Cipla. It brought the actions only because the filing would delay generic entry into the lenalidomide market. Cipla's ANDAs are "skinny labels" that seek only to treat multiple myeloma and myelodysplastic syndromes.

401. On August 15, 2017, Celgene filed a patent infringement action against Cipla, for filing ANDA No. 210435 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe the same combination of the '800 Patent, '217 Patent, '569

[148] https://www.businesswire.com/news/home/20190329005384/en/Celgene-Settles-U.S.-REVLIMID%C2%AE-Patent-Litigation-with-Alvogen.

Patent, ’498 Patent, ’095 Patent, ’621 Patent, and the ’622 Patent.[149] On May 8, 2018, Celgene filed another patent infringement action against Cipla, alleging Cipla’s ANDA would also infringe the ’357 Patent, ’219 Patent, and the ’598 Patent, none of which Celgene listed in the Orange Book as covering Revlimid.[150] On March 29, 2019, Cipla submitted a second ANDA, No. 213165. On July 3, 2019, Celgene filed another patent infringement action against Cipla, alleging Cipla’s second ANDA would infringe the ’800 Patent, the ’217 Patent, the ’569 Patent, the ’498 Patent, the ’095 Patent, the ’621 Patent, the ’622 Patent, the ’740 Patent, the ’717 Patent, and the ’120 Patent.[151] On May 12, 2020, Cipla submitted a third ANDA, No. 214618. On June 24, 2020, Celgene filed another patent infringement action against Cipla, alleging Cipla’s third ANDA would infringe the ’800 Patent, the ’217 Patent, the ’569 Patent, the ’498 Patent, the ’095 Patent, the ’621 Patent, the ’622 Patent, the ’740 Patent, the ’717 Patent, and the ’120 Patent.[152]

402. Cipla filed answers and counterclaims in all actions, alleging that all Celgene’s asserted patents are invalid, unenforceable, or uninfringed.

403. On January 14, 2019, the court ordered mediation between the parties. On February 6, 2019, the parties informed the court that *Markman* hearings were no longer necessary.

404. On April 30, 2019, the court issued a stipulated order in which the parties agreed not to contest a finding that products derived from Cipla’s ANDA would infringe Celgene’s

[149] *Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163 (D.N.J.).
[150] *Celgene Corp. v. Cipla Ltd.*, No. 2:18-cv-08964 (D.N.J.).
[151] *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J.).
[152] *Celgene Corp. v. Cipla Ltd.*, No. 2:20-cv-07759 (D.N.J.)

'357, '219, and '598 patents, none of which Celgene listed in the Orange Book as covering Revlimid, while Cipla reserved its rights to argue invalidity.

405. On May 28, 2020, Celgene filed its First Amended Complaint, alleging patent infringement arising from both of Cipla's ANDAs.[153] That day, the parties submitted their Joint Claim Construction Statement, informing the court of the absence of disputed terms. On June 8, 2020, Civil Action Nos. 18-08964 and 17-06163 were administratively terminated and incorporated by reference into Civil Action No. 19-14731.

406. On June 22, 2020, Cipla was granted leave to serve amended noninfringement contentions regarding Celgene's method of use patents for multiple myeloma.[154] On July 13, Celgene stipulated to a dismissal of its claims regarding the '217 Patent and filed a covenant not to sue Cipla for infringement of the '217 Patent.[155]

407. On August 21, 2020, Cipla submitted an application of fifteen single-spaced pages to the court seeking an order compelling Celgene's production of discovery. Celgene's opposition was due September 15. A telephone conference was set for November 23, 2020.

408. On December 11, 2020, Celgene announced a settlement agreement.[156] The terms of the agreement are confidential, but Celgene and Cipla announced some details in a press release that is identical to that released for the Dr. Reddy's and Lotus settlements,[157] indicating a similar settlement with another Later-Filing Generic designed to protect monopoly pricing.

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[153] First Amended Complaint, *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731, ECF No. 64 (D.N.J.).

[154] Stipulation and Order, No. 2:19-cv-14731, ECF No. 67 (D.N.J. June 22, 2020).

[155] Stipulation and Order of Dismissal, *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731, ECF No. 74 (D.N.J. Jul. 13, 2020).

[156] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Cipla.

[157] https://www.businesswire.com/news/home/20201211005052/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-with-Cipla.

409. The settlement agreement between Cipla and Celgene also served to shore up the anticompetitive reverse payment deal and complementary agreement. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Cipla. The volume-limited small caps ensure that Cipla has no incentive to compete on price (because, as with Natco, a price reduction does not increase output). As in the cases of the settlements with Natco, Dr. Reddy's, and Lotus, Celgene has no incentive to launch an AG. The net result of the agreement is that there will be no price competition, and Celgene retains its ability for a longer period to sell brand Revlimid at a monopoly pricing. The agreement with Cipla solidified, and was in part induced by, Celgene's agreements with Natco, Dr. Reddy's, and Lotus.

410. The anticompetitive effects of Celgene's conduct are to again delay and forestall price competition prevent in the lenalidomide market.

d. Celgene's Settles with Sun.

411. As part of its unlawful anticompetitive strategy, Celgene filed three serial patent infringement suits against Sun. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

412. In Spring 2018, Sun filed ANDA No. 211846 for generic lenalidomide. Sun's ANDA is a "skinny label" seeking only to treat multiple myeloma. On May 30, 2018, Sun sent written notice of its Paragraph IV certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Sun's ANDA.

413. On July 13, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Sun Pharmaceuticals Industries Inc. and related entities for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene

alleged would infringe its '800 Patent, '217 Patent, and '569 Patent.[158] On April 16, 2019, Celgene filed another patent infringement action against Sun, alleging that Sun's ANDA would infringe its '357 Patent, '219 Patent, and its '598 Patent, none of which Celgene listed in the Orange Book as covering Revlimid.[159] On February 2, 2021, Celgene filed another patent infringement action against Sun, alleging that Sun's ANDA would infringe its '498 Patent, '095 Patent, '621 Patent, and its '622 Patent.[160]

414. Sun filed answers and counterclaims in the first two actions (the third settled before Sun filed an Answer), alleging that all Celgene's asserted patents are invalid, unenforceable, or uninfringed.

415. On January 22, 2019, Celgene filed a Statement informing the court of its covenant not to sue Sun for infringement of the '217 Patent.[161]

416. On December 12, 2019, the court cancelled *Markman* hearings upon the parties' joint motion.

417. On June 21, 2021, Sun announced its settlement with Celgene.[162] The only details made available were that "Celgene will grant Sun Pharma a license to Celgene's patents required to manufacture and sell (subject to USFDA approval) certain limited quantity of generic lenalidomide capsules in the US beginning on a confidential date that is sometime after March 2022. In addition, the license will also allow Sun Pharma to manufacture and sell an unlimited

[158] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:18-cv-11630 (D.N.J.).
[159] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:19-cv-10099 (D.N.J.).
[160] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.*, No. 2:21-cv-01734 (D.N.J.).
[161] Statement, *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al*., No. 2:18-cv-11630, ECF No. 50 (D.N.J. Jan. 22, 2019).
[162] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Sun.

quantity of generic lenalidomide capsules in the US beginning January 31, 2026."[163] The terms of the agreement are confidential, but Celgene and Sun announced some details in a press release that is identical to that released for the Dr. Reddy's, Lotus, and Cipla settlements, indicating a similar settlement to another Later-Filing Generic.[164] As in the cases of the settlements with Natco, Dr. Reddy's, and Lotus, Celgene has no incentive to launch an AG. The net result of the agreement is that there will be no price competition, and Celgene retains its ability for a longer period to sell brand Revlimid at a monopoly pricing. The agreement with Sun also solidified, and was in part induced by, Celgene's earlier agreements with Natco, Dr. Reddy, Lotus, and Cipla.

418. The anticompetitive effects of Celgene's conduct are to again delay and forestall price competition prevent in the lenalidomide market.

4. The Settlement Between Celgene and Natco, is an Anticompetitive Reverse Payment Agreement that Resulted in a Market Division and Delayed True Generic Competition.

419. The Celgene-Natco agreement is an anticompetitive reverse payment condemned by the Supreme Court in *FTC v. Actavis.* The reverse payment took the form of volume-limited royalty-free licenses prior to full-fledged and robust competition,[165] as well as most-favored entry clauses. The agreement is also, separate and apart from whether it includes payments, an illegal market allocation among competitors. The agreement delayed full-fledged and robust competition and resulted in an anticompetitive market division that benefited the parties involved to the detriment of purchasers.

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[163] https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf

[164] https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf

[165] Prior to full disclosure of the actual agreement(s) and discovery, quantification of the payment is approximate.

a. *Bona fide* Generic Competition Will Not Begin Until January 31, 2026, Causing Plaintiff to Suffer Substantial Overcharges on its Purchases of Revlimid.

420. The Revlimid anticompetitive reverse payment settlement and complementary agreements will prevent true generic competition for Revlimid until January 31, 2026. As a result, Plaintiff will be and has been forced to purchase brand Revlimid at supra-competitive prices through at least early 2026, even with the volume-limited introduction of Natco's generic Revlimid (marketed by Teva) in March of 2022.

421. Absent Celgene's multipronged monopolistic scheme, generic Revlimid would have been available years ago, on a date to be determined during discovery.

422. Absent the Revlimid agreements, a reasonable generic company in the position of Natco/Teva would have launched: (i) launched generic Revlimid after prevailing at trial, (ii) launched at risk, or (iii) entered into a payment-free agreement that provided for an earlier agreed entry date. At the very latest, absent the Revlimid agreements, Natco/Teva would have at least been able to launch on May 21, 2021, after receiving final approval from the FDA or – in the absence of entering into an anticompetitive payment-laded agreement with competitor Celgene – even earlier. As above, Dr. Reddy's would have been able to launch two formulations of generic Revlimid soon thereafter, having itself received final approval on October 14, 2021 or – in the absence of entering into an anticompetitive payment-laded agreement with competitor Celgene – even earlier. From what is known and alleged in this Complaint, including the improperly listed and later invalidated REMS patents (expired 2020) and the known defects of the '517 Patent (expired 2019), generic entry would have likely occurred substantially earlier.

423. A 2010 study by the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%, findings confirmed by later studies. Given that there were

multiple generic filers, it is likely that additional generics would have entered subsequent to Natco, driving down prices in accord with industry experience.[166] Thus, Plaintiff will suffer substantial damages in overcharges on Revlimid purchases through at least early 2026.

424. A seller with a volume limit has no incentive to compete on price. Adding generic sellers with volume limits will put no downward pressure on price.

425. If reasonable, competitively-acting companies in the position of Natco and Celgene had chosen to settle lawfully, i.e., without a market allocation and/or large and unjustified payment, the agreed upon date by which Natco could enter with its generic Revlimid would have been earlier, well before March of 2022 and robust generic competition would have occurred well before January 31, 2026.

426. Because of the delayed date of robust competition, and Celgene's multifaceted monopolistic scheme, Celgene had extra time to convert the bulk of Thalomid prescriptions over to Revlimid prescriptions, thereby taking advantage of its artificially and unlawfully extended monopoly on Revlimid and the supracompetitive prices caused by its misconduct.

b. Volume Limited, Royalty-Free Licenses Prior to True Generic Competition as a Reverse Payment.

427. As discussed above, Celgene's settlement agreement with Natco provides for a volume-limited, royalty-free license. Natco described the existence of, but not the precise numbers, of the volume limits in its original press release. Additionally, during Natco's February 12, 2016 earnings call (held shortly after the Natco Revlimid settlement was announced), Natco CEO Rajeev Nannapaneni stated with respect to the Revlimid settlement

[166] *See* R. Conrad and R. Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA: Generic Competition and Drug Prices (December 2019), available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (last accessed March 29, 2022).

agreement: "We have a launch date. The launch date is clear. It allows us to launch *without paying a license fee* that is the arrangement that we have."[167]

428. The volume-limited, royalty-free license is essentially a side deal wherein the brand pays the generic by allowing some sales during a period protected from generic competition. In an arm's length agreement where the volume-limited license were not connected to a delayed date for full generic competition, a reasonable, competitively-acting company in the position of Celgene would have kept the large majority of profits prior to full generic entry by charging Natco a substantial royalty. By instead offering a favorable royalty payment as part of a patent litigation settlement, or by waiving it entirely, as Celgene did when settling the Revlimid litigation with Natco, a brand manufacturer makes a substantial reverse payment to the generic manufacturer.

429. Similar, competitive agreements that are unconnected to patent litigation settlements provide a close analogy to an arm's length transaction. Brand manufacturers sometimes launch their own generic product before full-fledged generic entry occurs.[168] When

[167] Natco Feb. 12, 2016 earnings call transcript at p. 20, available at https://natcopharma.co.in/wp-content/uploads/2016/02/NirmalBang-NatcoPharma-Feb12-2016.pdf (last accessed March 2, 2022).

[168] Although brand AG products are typically launched upon generic entry (see FTC 2011 Report, p. 74), numerous brand manufacturers have employed the strategy of preempting generic competition with an earlier AG launch. For example, brand manufacturers employed this strategy with AG launches of the drugs Xanax, Dyazide, Lopid, Tenormin, and Naprosyn. See J. Peny and R. Young, "Are generic defence strategies worth the effort?" *Scrip Magazine*, June 1996 (https://smart-pharma.com/wp-content/uploads/2019/07/Ethical-Products_Are-generics-defense-strategies-worth-the-effort.pdf); "Geneva Pharmaceuticals has First Legitimate AB-Rated Generic Dyazide," *The Pink Sheet*, August 5, 1991 (https://pink.pharmaintelligence.informa.com/PS019523); "Warner-Lambert will Launch Generic Lopid; Is 'Discussing' Triglycerides Claim for Lopid SR with FDA, Company Tells Analysts in 'Life after Lopid' Talk," *The Pink Sheet*, April 27, 1992 (https://pink.pharmaintelligence.informa.com/PS020773); and "Arthritis Drug Maker Losing Its Monopoly: Pharmaceuticals: As its patent runs out, Syntex faces another challenger. Analysts

the brand launches its own generic through a distributor in a competitive agreement that is unconnected to patent litigation, the industry standard is for the brand to retain 90% or more of the licensed generic profits.[169] A rational brand manufacturer in Celgene's position would not waive these royalties unless it was getting something in return. Celgene charged no royalties to Natco during the limited-volume period because the license was indeed connected to the patent litigation settlement and it was getting something in return: Celgene was buying a delay in full-fledged, robust, generic competition.

430. While at this stage precise calculation of the size of the payment cannot be made, by any view the transfer of value to Natco in the settlement agreement is massive. By way of illustration, a three-year, volume-limited license starting at 5% and over time moving to an allocation of 30% of the market to the Natco generic[170] would result in a reverse payment from the brand manufacturer to Natco of approximately $3.6 billion.[171] As shown below:

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are predicting a 'ruthless market,'" *L.A. Times*, September 30, 1993 (https://www.latimes.com/archives/la-xpm-1993-09-30-fi-40495-story.html).

[169] FTC 2011 study at p. 77 ("Apart from contexts where AG marketing rights derive from patent litigation settlements, marketing agreements generally require AG distributors to pay the brand a large percentage of profits on the AG, typically from 50–92 percent"); *id.* at fn. 55 ("CD, Oct. 12, 2004 ('Historically, generic partners received 20–35% of the economics, but this has now been driven down to 10% or less')"); *see also* presentation entitled "Authorized Generic Partnership: Merck – Ranbaxy" dated May 24, 2007 (PDF labeled "Nexium Trial Exhibit 103"), which states, "Current industry standard for sharing Net Profits is 90% to the innovator company and 10% to the generic marketer." Some brand companies retain all the profit by launching AGs "in house" through a subsidiary.

[170] As described above, Natco was set to receive "a mid-single-digit percentage" of the volume during the first year after entry, which was set "increase gradually each 12 months" and was "not expected to exceed one-third of the total" volume in the third year of the Agreement. Press Release, Celgene Corp., *Celgene Settles REVLIMID® Patent Litigation* (Dec. 22, 2015), http://ir.celgene.com/releasedetail.cfm?ReleaseID=947998.

[171] The Revlimid market is conservatively assumed to remain at $8 billion in each year. Reasonable parties in Celgene and Natco's positions likely would have expected it to be greater. Also, as discussed above, there is no incentive for the generic to compete on price with a volume limited license, so the generic-to-brand price ratio is 100%.

	Brand Market (in millions)	Percent of market	Generic-to-brand price ratio	Generic sales (in millions)	Foregone royalties on generic sales (in millions)
Year 1	$8,000	5.0%	100%	$400	$360
Year 2	$8,000	15.0%	100%	$1,200	$1,080
Year 3	$8,000	30.0%	100%	$2,400	$2,160
				Total:	**$3,600**

431. Celgene also agreed to provide volume-limited licenses to at least four of the Later-Filing Generics to start "sometime after March 2022" and likely limited to a "low-single digit percentage" of the market.[172] Celgene has continued to conceal the terms of these settlements, including whether they involve a below market rate royalty. However, the settlements with LFGs are at least complementary agreements that Celgene settled on terms that shored up the anticompetitive terms (and attendant windfall) of the anticompetitive reverse payment to Natco. The total size of the reverse payment from Celgene to Natco associated with these foregone royalties is estimated to be $3.6 billion.

c. Most-Favored Entry Clauses.

432. Second, Celgene made a payment to Natco in the form of a most-favored entry (alternative, "acceleration") clause, that would provide disincentives to later generics to continue to challenge the Revlimid patents. If a later (non-settling) generic were to continue the litigation

[172] *See* https://www.businesswire.com/news/home/20200917005211/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-With-Dr.-Reddy%E2%80%99s; https://www.businesswire.com/news/home/20190329005384/en/Celgene-Settles-U.S.-REVLIMID%C2%AE-Patent-Litigation-with-Alvogen.; https://www.businesswire.com/news/home/20201211005052/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-with-Cipla; https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf.

and invalidate the patents, triggering the most-favored entry clause, it would allow at least Natco to enter the market early, cutting into the non-settling generic's market share and causing further price erosion. In other words, the challenger would bear 100% of the cost and risk associated with continuing the patent challenge but would enjoy only a fraction of the rewards if it were to succeed. As a result, most-favored entry clauses deter patent challenges and provide a payment to the settling generic in the form of an assurance that it will receive the most-favorable entry date.

433. Natco has disclosed that the Revlimid settlement agreement contains a most-favored entry clause, which if triggered, would or will permit Natco to enter the market earlier than it otherwise would be allowed under the terms of the settlement agreement. One of the events that can trigger the most-favored entry clause is if another generic manufacturer pursues the patent litigation and succeeds in invalidating Celgene's patents.[173] Without the clause, Natco would forfeit its lucrative 180-day exclusivity period if it could not launch within 75 days of the legal decision. The clause would allow Natco to launch quickly and retain its exclusivity, thus eliminating the risk that Natco could lose the 180-day exclusivity period.[174] This elimination of the risk of losing the exclusivity period was extremely valuable to Natco.

d. The Anticompetitive Reverse Payment and Complementary Agreements Delayed Generic Competition and Created an Anticompetitive Market Division.

434. Celgene's agreements with Natco and the Later-Filing Generics delayed full-fledged generic entry by creating an anticompetitive market division. As summarized in Table X,

[173] Other common forms of most favored entry clauses allow the settling generic to enter if a different generic launches at risk or gets an earlier licensed entry date.

[174] Keith Drake and Thomas McGuire, *Most Favored Entry Clauses in Drug Patent Litigation Settlements as a Potential Reverse Payment*, National Bureau of Economic Research, Working Paper 29801 (February 2022), available at https://www.nber.org/papers/w29801 (last accessed March 8, 2022).

compared to true generic entry, the market division benefits Celgene, Natco, and the Later Filing Generics at the expense of Purchasers.

Table X Market Division Created by the Anticompetitive Reverse Payment Settlements

	Celgene			Third-Party	Purchaser
	Brand	AG	Natco	Generics	Spending
Competitive Conditions					
180-days	0.40	0.84	0.84		2.07
Next 2.5 years	2.00	0.18	0.18	0.73	3.10
Total	2.40	1.02	1.02	0.73	5.17
Reverse Payment Agreements					
Year 1	7.12		0.40	0.48	8.00
Year 2	5.52		1.20	1.28	8.00
Year 3	4.00		2.40	1.60	8.00
Total	16.64	0.00	4.00	3.36	24.00
Anticompetitive Profit	14.24	-1.02	2.98	2.63	
Harm to Purchasers					18.83

435. To make these calculations, the market is conservatively assumed to be $8 billion in each year with no price competition. Without volume limits, generics are assumed to capture 90% of the overall unit volume and generic prices are assumed to be as specified by the generic-to-brand price ratios calculated by the FDA.[175]

436. Under competitive conditions, with full-fledged generic entry, Celgene would make approximately $3.4 billion. During the first 180 days after generic entry, Celgene would make $0.4 billion from its brand sales ($4 billion * 10% brand-generic market share) and $0.84 billion in authorized generic sales ($4 billion * 90% brand-generic market share * 46.5% generic-to-brand price ratio * 50% of the generic market). Over the next two-and-a-half years, Celgene would make another $2 billion in brand sales ($8 billion * 2.5 years * 10% brand-

[175] https://www.fda.gov/media/133509/download (last page)

generic market share) and $0.18 billion in authorized generic sales ($8 billion * 2.5 years * 90% brand-generic market share * 6.1% brand-to-generic price ratio * 1/6 of the generic market).

437. With the market division in place, Celgene would earn $16.6 billion, approximately $14.2 billion more than under competitive conditions. Because its brand product could retain whatever share of the market Celgene did not allocate to the generics, Celgene would have no incentive to launch an authorized generic (which would typically enhance generic competition if no volume caps were in place). Assuming that Natco and the Later Filing Generics are allocated the same shares of the market as above, Celgene's sales are calculated as: $8 billion * (100% - 5% volume to Natco – 1.5% * 4 volume to Later Filing Generics) + $8 billion * (100% - 15% volume to Natco – 4% * 4 volume to Later Filing Generics) + $8 billion * (100% - 30% volume to Natco - 5% * 4 volume to Later Filing Generics) = $16.6 billion.

438. As shown, Natco is also better off with the market division agreement in place compared to with competitive conditions, by approximately $3.0 billion. With competitive conditions, Natco's generic sales are similar to Celgene's authorized generic sales of $1.02 billion ($0.84 billion during the exclusivity period and $0.18 billion over the next 2.5 years). With the market division in place, Natco captures less of the generic market but benefits from the lack of price competition. Natco's sales across the three-year period total $4.0 billion ($8 billion * 5% market share + $8 billion * 15% market share + $8 billion * 30% market share).

439. The Later-Filing Generics are also better off with the market division agreement in place, by about $2.6 billion. Under competitive conditions, they collectively make $0.73 billion ($8 billion * 2.5 years * 90% brand-generic market share * 6.1% brand-to-generic price ratio * 4/6 of the generic market). With the market division agreement, they make $3.4 billion ($8 billion * 1.5% * 4 volume to Later Filing Generics + $8 billion * 4% * 4 volume to Later

Filing Generics + $8 billion * 5% * 4 volume to Later Filing Generics). Each generic makes approximately $0.7 billion more under the market division agreement ($2.6 billion / 4 generics) compared to with competitive conditions.

440. In total, Celgene, Natco, and the Later-Filing Generics' sales increase by $18.8 billion with the market division agreement compared to competitive conditions. The increased sales of all the sellers of the brand and generic Revlimid come at the expense of Purchasers.

e. Although Similar to a No-AG Clause, the Market Division Created by the Volume-Limited Licenses Results in Even More Harm to Purchasers

441. With competitive conditions, there are typically three products available during the 180-day generic exclusivity period: the first-to-file generic's product, the brand's authorized generic product, and the brand product. As summarized above, the two generic products quickly capture most of the market. The generics compete on price, bringing it down to approximately 46.5% of the brand price, so purchasers benefit.

442. A no-AG clause is an anticompetitive promise from the brand not to compete with the generic during the 180-day exclusivity period (made in exchange for a delay in generic entry). However, there are still two competitors and the generic must price below the brand product to capture most of the market. According to the FDA, a generic product in a market with only one generic seller is priced at 61.4% of the brand price.[176] There is less benefit to purchasers compared to if there had been two generic products, but the competition introduced by one generic making unrestricted sales still benefits purchasers.

[176] R. Conrad and R. Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA: Generic Competition and Drug Prices (December 2019), available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (last accessed March 29, 2022).

443. With a volume-limited license, the brand can retain whatever share of the market it has not allocated to the generic, so there is no incentive to launch an authorized generic. For the volume-restricted generic, its sales volume is also fixed and it has no incentive to try to increase volume by reducing price. Without some price competition, purchasers do not benefit from volume-limited generic entry.

444. The market division agreement here is more harmful to purchasers than a traditional no-AG clause for another reason. With a no-AG clause, after the 180-day exclusivity period expires, later-filing generics typically enter and drive down the price much further towards marginal cost. With respect to Revlimid, Celgene also allocated small shares of the market to the Later Filing Generics, so they will also have no incentive to compete on price. Thus, even after more generics become available, the price will remain close to the brand price and purchasers will derive very little if any benefit. In other words, a no-AG clause keeps the generic price unduly high for 180-days, but the Revlimid market division will keep it even higher and for a longer period of almost three years. (Of course, both arrangements also result in delaying generic competition.)

5. Celgene and Remaining Later-Filing Generics Quietly Settle Sham Litigations

445. Celgene continued to file patent infringement litigation against any generic Revlimid ANDA filer. Only the Alembic sham patent litigation remains pending. Celgene and the below Later-Filing Generics have kept *all* the terms of their settlement agreements confidential. However, Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the below settlement agreements will likely reveal anticompetitive

provisions that have shielded Celgene's patents from judicial scrutiny and delayed generic competition.

a. Celgene's Sham Litigation Against Apotex

446. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Apotex. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

i. Polymorphic Forms and Methods-of-Use Patents

447. After Apotex filed its ANDA for generic lenalidomide, it sent written notice of its Paragraph IV certification to Celgene on November 28, 2017, alleging that the patents-in-suit are invalid and/or will not be infringed by Apotex's ANDA.

448. On January 11, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Apotex for filing ANDA No. 211022 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '720 patent, '977 Patent, '784 Patent, '886 Patent, '531 Patent, '800 Patent, '217 Patent, '363 Patent, and '929 Patent.[177]

449. On August 30, 2018, Apotex filed its answer and affirmative defenses, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed. Apotex alleged that five of the patents-in-suit are unenforceable due to patent misuse because Celgene asserted the patents even though no reasonable litigant could believe they were valid in light of prior proceedings in front of the PTAB.

450. On January 14, 2019, the District Court referred the parties to mediation.

[177] *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461 (D.N.J.).

451. On January 22, 2019, the District Court entered a statement executed by both Celgene and Apotex in which Celgene covenanted not to sue Apotex Inc. ("Apotex"), or its successors in interest, for infringement of the '217 Patent based on the filing of ANDA No. 211022 or its past, present, or future manufacture, use, sale, and offer for sale, in the United States, or importation into the United States, of a generic version of Celgene's Revlimid® product, as presently described in ANDA No. 211022. The statement nonetheless included that Celgene did not concede that the '217 Patent is not infringed, is invalid, or is unenforceable.

452. Per the scheduling order, Apotex was to serve its invalidity and non-infringement contentions on February 15, 2019, with Celgene to serve its infringement contentions on April 26.

453. Four days after Celgene was to serve its infringement contentions, on April 30, 2019, the District Court issued a consent judgment that the '217 Patent was not infringed by ANDA No. 211022. Thus, judgment of non-infringement was entered in favor of Apotex and against Celgene as to infringement of the '217 Patent, Celgene's Polymorph patent.[178]

454. The following week, on May 8, 2019, the District Court issued an order bifurcating the claims and staying the action as to the '720 Patent, '977 Patent, '784 Patent, '886 Patent, and '531 Patent, Celgene's REMS patents. As described above, Celgene's REMS patents are likely invalid as obvious—as shown by the Federal Circuit's invalidation of the '720 Patent—and Celgene likely stayed litigation of these patents in order to protect them from invalidation, thereby preserving its ability to sue on them and still trigger a 30 month stay of FDA approval. Apotex asserted affirmative defenses that these patents were also invalid for

[178] Consent Judgment, *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461, ECF No. 63 (D.N.J. Apr. 30, 2019).

patent misuse, as no reasonable litigant could believe they were valid in light of PTAB's invalidation of the '720 Patent. The remaining patents share the same specifications as the '720 Patent and have similar claims.

455. Like Natco, Apotex asserted defenses that the '800 Patent is invalid under 35 U.S.C. § 112 for indefiniteness, lack of written description, and lack of enablement. The '800 Patent is one of two key patents in Celgene's scheme, covering—along with the non-infringing '217 Patent—polymorphic forms of the lenalidomide compound.

456. On August 9, 2019, following extensions, the parties entered joint claim construction and prehearing statements indicating that no claim construction was needed to resolve all claims relating to the remaining patents at issue.

457. On January 13, 2021 the District Court entered a new scheduling order as to expert discovery regarding still pending claims concerning the remaining patents at issue, including the '800 patent. Per the order, polymorph patent expert reports were due on February 18.

458. On March 10, 2021, Celgene and Apotex stipulated and consented to an entry of judgment and an injunction prohibiting Apotex from marketing its generic lenalidomide, "except as specifically authorized by Celgene," until the expiration of the patents-in-suit listed above pursuant to a settlement agreement.[179]

459. Neither Celgene nor Apotex issued a press release and the terms of the settlement agreement are not publicly available.

ii. Additional Methods-of-Use Patents

[179] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Apotex.

460. On February 26, 2019, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Apotex for filing ANDA No. 211022 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '740 Patent, '717 Patent, and '120 Patent.[180]

461. On December 2, 2019, the parties submitted a joint claim construction statement advising the court that no *Markman* order was needed.

462. On January 13, 2021 the District Court entered a new scheduling order as to expert discovery regarding still pending claims concerning the outstanding patents at issue.

463. As detailed above, the parties on March 10, 2021, stipulated to a dismissal and injunction, covering the '740 Patent, '717 Patent, and '120 Patent. Details of this settlement agreement are not publicly available.

464. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[181]

iii. Additional Litigation

465. On June 19, 2019, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Apotex for filing ANDA No. 211022 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '357 Patent, '219 Patent, and '598 Patent.[182]

[180] *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-06999 (D.N.J.).

[181] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Apotex.

[182] *Celgene Corp. v. Apotex Inc.*, No. 2:19-cv-13994 (D.N.J.).

466. On February 27, 2020, the parties submitted a joint claim construction statement advising the court that no *Markman* order was needed.

467. On January 13, 2021, the District Court entered a new scheduling order as to expert discovery regarding still pending claims concerning the outstanding patents at issue.

468. The parties on March 10, 2021, stipulated to a dismissal and injunction, covering the patents in suit. Apotex is prohibited from marketing a generic lenalidomide, "except as specifically authorized by Celgene." Details of this settlement agreement are not publicly available.

469. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.

b. Celgene's Sham Litigation Against Zydus

470. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Zydus. It brought the actions only because the filing would delay generic entry into the lenalidomide market. Although Zydus obtained Temporary Approval on August 16, 2021, it still has not launched a generic Revlimid. But for Celgene's anticompetitive scheme, Zydus would have gained temporary and final approval far earlier and launched a competing product.

i. Polymorphic Form and Methods-of-Use Patents

471. On April 12, 2017, Celgene filed a patent infringement action against Zydus and its healthcare arm, Cadila Healthcare Limited, for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly infringing Celgene's same '800 Patent, '217

Patent, ’569 Patent, ’498 Patent, ’095 Patent, ’621 Patent, and ’622 Patent.[183] This combination of patents has become central to Celgene’s strategy of blocking generic competitors.

472. On August 7, 2017, Zydus filed its answer and counterclaimed that each of Celgene’s asserted patents are invalid, unenforceable, or noninfringed.

473. On August 8, 2018, Celgene filed a Statement informing the court of its covenant not to sue Zydus for infringement of the ’217 Patent.[184]

474. On December 17, 2018, Celgene and Zydus stipulated that the parties had no disputed terms requiring claim construction.

475. On January 14, 2019, the court ordered mediation between the parties.

476. On May 10, 2019, the court issued an Amended Scheduling Order.

477. On March 13, 2020, Celgene filed a motion to stay proceedings, filed under seal, which was denied on September 3, 2020. On March 24, 2021, the Court entered a consent judgment, dismissing the matter with prejudice pursuant to a settlement agreement.

ii. Additional Polymorphic Form Patents

478. On April 27, 2018, Celgene filed yet another patent infringement action against Zydus for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene’s ’357 Patent, ’219 Patent, and ’598 Patent.[185]

479. On July 9, 2018, Zydus filed its Answer.

480. On January 14, 2019, the court ordered mediation between the parties. Fact discovery closed on August 30, 2019.

[183] *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:17-cv-02528 (D.N.J.).
[184] Statement, *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:17-cv-02528, ECF No. 93 (D.N.J. Aug. 8, 2018).
[185] *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:18-cv-08519 (D.N.J.).

481. On March 13, 2020, three years after filing suit, In briefing now partially redacted, Celgene argued that because samples provided by Zydus two years prior were expired that an indefinite stay was warranted.[186] On September 3, the District Court denied the stay during a hearing, the minutes of which have been sealed.

482. On March 24, 2021, the Court entered a consent judgment in both of the patent infringement actions that Celgene brought against Zydus, wherein Zydus agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Zydus' generic version of Revlimid in the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico, until the expiration of Celgene's '800 Patent, '569 Patent, '357 Patent, '219 Patent, '598 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent, "except as provided for in the settlement."[187]

483. Details of this settlement agreement are not publicly available. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[188]

c. Celgene's Sham Litigation Against Hetero

[186] REDACTED Opposition to Motion to Stay, *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 2:18-cv-08519, ECF No. 116 at 4-5, 12-13 (D.N.J. Mar. 12, 2021).

[187] Consent Judgment, ECF 210, No. 2:17-cv-02528, ECF 119, No. 2:18-cv-08519 (D.N.J. Mar. 24, 2021).

[188] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Zydus.

484. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Hetero. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

i. Polymorphic Forms and Methods-of-Use Patents

485. In fall 2018, Hetero filed its ANDA for generic lenalidomide. On November 9, 2018, Hetero sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Hetero's ANDA.

486. On December 20, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Hetero Labs Ltd.[189] for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, '363 Patent, and '929 Patent.[190]

487. On March 11, 2019, Hetero filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed. On April 15, 2019, Celgene filed its answer to Hetero's counterclaim.

488. On January 21, 2020, the District Court entered a stipulation dismissing without prejudice Celgene's claims relating to the '217 Patent, '363 Patent, and the '929 Patent, leaving the case at that point only pending with respect to only the '800 Patent.[191]

489. On October 26, the parties submitted final *Markman* briefings.

[189] The complaint also named Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero").

[190] *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2:18-cv-17463 (D.N.J.).

[191] Stipulation, *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2:18-cv-17463, ECF No. 54 (D.N.J Jan. 21, 2020).

490. On January 11, 2021, the District Court entered an order administratively terminating the docket, with the action consolidated under lead docket 2:20-cv-14389, detailed below.

491. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and forestall price competition in the lenalidomide market.

ii. Additional Methods-of-Use Patents

492. On July 16, 2019, Celgene filed yet another patent infringement action against Hetero for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would also infringe its '740 Patent, '569 Patent, '717 Patent, '498 Patent, '095 Patent, '120 Patent, '621 Patent, and '622 Patent.[192]

493. On October 11, 2019, Hetero filed its answer and counterclaims against Celgene, for which Celgene filed an answer on November 15, 2019.

494. On December 18, 2019, the court issued a pretrial scheduling order. On October 26, 2020, the parties submitted final *Markman* briefs.

495. On January 11, 2021, the District Court entered an order administratively terminating the docket, with the action consolidated under lead docket 2:20-cv-14389, detailed below.

496. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and forestall price competition in the lenalidomide market.

iii. Additional Litigation

[192] *Celgene Corp. Hetero Labs Ltd., et al.*, No. 2:19-cv-15449 (D.N.J.).

497. On October 13, 2020, Celgene filed another patent infringement action against Hetero for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '357 Patent and '219 Patent.[193]

498. On January 8, 2021, Celgene filed an Amended Complaint, incorporating the claims asserted in the other two, administratively terminated, dockets.

499. On May 7, 2021, the parties submitted a joint claim construction statement.

500. On September 27, 2021, Celgene and Hetero stipulated and consented to an entry of judgment and an injunction prohibiting Hetero from marketing lenalidomide, "unless and to the extent otherwise specifically authorized by Celgene," until the expiration of the patents-in-suit listed above pursuant to a settlement agreement.[194] The terms of the settlement agreement are not publicly available. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[195]

d. Celgene's Sham Litigation Against Mylan

501. In winter 2019, Mylan filed its ANDA for generic lenalidomide. On November 20, 2019, Mylan sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Mylan's ANDA.

[193] *Celgene Corp. Hetero Labs Ltd., et al.*, No. 2:20-cv-14389 (D.N.J.).

[194] Consent Judgment, *Celgene Corp. Hetero Labs Ltd., et al.*, No. 2:20-cv-14389, ECF No. 51 (D.N.J. Sep. 27, 2021).

[195] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Hetero.

502. On December 31, 2019, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Mylan in the District of New Jersey for filing ANDA No. 213912 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '740 patent, '800 Patent, '217 Patent, '569 Patent, '717 Patent, '498 Patent, '095 Patent, '120 Patent, '621 Patent, and '622 Patent ("New Jersey action").[196]

503. Also, on January 3, 2020, Celgene filed an identical complaint against Mylan in the Northern District of West Virginia ("West Virginia action"), alleging infringement of the same patents as in the New Jersey action.[197]

504. On October 9, 2020, in the West Virginia action, Celgene submitted a covenant not to sue Mylan on the '217 Patent.[198]

505. On November 16, 2020, the parties submitted, in the West Virginia action, a joint claim construction statement agreeing that there were no disputed terms requiring claim construction. On April 23, 2021, Mylan filed its Amended Answer and Counterclaims to Celgene's Amended Complaint.

506. On July 23, 2021, Mylan and Celgene stipulated and consented to an entry of judgment in both actions and an injunction prohibiting Mylan from marketing its generic lenalidomide, "unless and to the extent otherwise specifically authorized by Celgene," until the expiration of the patents-in-suit listed above pursuant to a settlement agreement. The terms of the settlement agreement are not publicly available. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the

[196] *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 2:19-cv-22231 (D.N.J.).
[197] *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:20-cv-00003 (N.D. W. Va.).
[198] Statement, *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:20-cv-00003, ECF No. 120 (N.D. W. Va. Oct. 9, 2020).

little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[199]

e. Celgene's Sham Litigation Against Aurobindo

507. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Aurobindo. It brought the actions only because the filing would delay generic entry into the lenalidomide market. Although Aurobindo obtained Temporary Approval on March 8, 2022, it still has not launched a generic Revlimid. But for Celgene's anticompetitive scheme, Aurobindo would have gained temporary and final approval far earlier and launched a competing product.

i. Polymorphic Forms and Methods-of-Use Patents

508. In Winter 2019, Aurobindo filed ANDA No. 213885 for generic lenalidomide. On November 25, 2019, Aurobindo sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Aurobindo's ANDA.

509. On January 8, 2020, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Aurobindo Pharma Ltd., Aurobindo Pharma U.S.A., Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Ltd. (collectively, "Aurobindo") for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent.[200]

[199] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Mylan.

[200] *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2:20-cv-00315 (D.N.J.).

510. On March 27, 2020, Aurobindo filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

511. On July 19, 2021, Aurobindo and Celgene stipulated and consented to an entry of judgment and an injunction prohibiting Aurobindo from marketing its generic lenalidomide until the expiration of the patents-in-suit listed above pursuant to a settlement agreement. The terms of the settlement agreement are not publicly available. The terms of the settlement agreement are not publicly available. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[201]

ii. Additional Litigation

512. On January 12, 2021, Celgene filed another patent infringement action against Aurobindo Pharma Ltd., Aurobindo Pharma U.S.A., Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Ltd. (collectively, "Aurobindo") for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '357 Patent, '219 Patent, and '598 Patent.[202]

513. On April 15, 2021, Aurobindo filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

514. On July 19, 2021, Aurobindo and Celgene stipulated and consented to an entry of judgment and an injunction prohibiting Aurobindo from marketing its generic lenalidomide,

[201] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Aurobindo.

[202] *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2:21-cv-00624 (D.N.J.).

"unless and to the extent otherwise specifically authorized by Celgene," until the expiration of the patents-in-suit listed above pursuant to a settlement agreement. The terms of the settlement agreement are not publicly available. The terms of the settlement agreement are not publicly available. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed generic competition.[203]

f. Celgene's Sham Litigation Against Lupin

515. In Summer 2020, Lupin filed ANDA No. 214398 for generic lenalidomide. On May 26, 2020, Lupin sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Lupin's ANDA.

516. On July 9, 2020, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Lupin Limited for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent.[204]

517. On August 5, 2020, Lupin filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

518. On February 19, 2021, the parties submitted a joint statement advising the court that the parties did not dispute any claim terms.

519. On June 30, 2021, Celgene filed an amended complaint.

[203] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Aurobindo.

[204] *Celgene Corp. v. Lupin Ltd.*, No. 2:20-cv-08570 (D.N.J.).

520. On September 15, 2021, the Court entered an Amended Scheduling Order, requiring the parties to serve their infringement and invalidity contentions by October 12.

521. On December 14, 2021, Lupin and Celgene stipulated and consented to an entry of judgment in both actions and an injunction prohibiting Lupin from marketing its generic lenalidomide, "unless and to the extent otherwise specifically authorized by Celgene," until the expiration of the patents-in-suit listed above pursuant to a settlement agreement. The terms of the settlement agreement are not publicly available. The terms of the settlement agreement are not publicly available. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[205]

g. Celgene's Sham Litigation Against Hikma

522. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Hikma. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

i. Polymorphic Forms and Methods-of-Use Patents

523. In early 2021, Hikma filed ANDA No. 213103 for generic lenalidomide. On March 15, 2021, Hikma sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Aurobindo's ANDA.

524. April 28, 2021, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Hikma for filing its ANDA for various dosages of its

[205] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Lupin.

generic alternative to Revlimid, which Celgene alleged would infringe its '740 Patent, '800 Patent, '217 Patent, '569 Patent, '717 Patent, '498 Patent, '095 Patent, '120 Patent, '621 Patent, and '622 Patent.[206]

525. On June 22, 2021, Hikma filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

526. On January 13, 2022, Hikma and Celgene stipulated and consented to an entry of judgment in both actions and an injunction prohibiting Hikma from marketing its generic lenalidomide until the expiration of the patents-in-suit listed above pursuant to a settlement agreement. The terms of the settlement agreement are not publicly available. Plaintiff believes that, given the above pattern of anticompetitive reverse payment agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[207]

ii. Additional Litigation

527. On December 10, 2021, Celgene filed another patent infringement action against Hikma for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '357 Patent, '219 Patent, and '598 Patent.[208]

528. Only one month later on January 13, 2022, as above, Hikma and Celgene stipulated and consented to an entry of judgment in both actions and an injunction prohibiting Hikma from marketing, "unless and to the extent otherwise specifically authorized by Celgene," its generic lenalidomide until the expiration of the patents-in-suit listed above pursuant to a

[206] *Celgene Corp. v. Hikma Pharmaceuticals USA, Inc.*, No. 2:21-cv-10398 (D.N.J.).
[207] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Hikma.
[208] *Celgene Corp. v. Hikma Pharmaceuticals USA, Inc.*, No. 2:21-cv-20459 (D.N.J.).

settlement agreement.[209] The terms of the settlement agreement are not publicly available. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[210]

h. Celgene's Sham Litigation Against Biocon

529. In Spring 2021, Biocon filed ANDA No. 215759 for generic lenalidomide. On April 1, 2021, Torrent sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Torrent's ANDA.

530. On May 14, 2021, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Biocon for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '740 Patent, '800 Patent, '217 Patent, '569 Patent, '717 Patent, '498 Patent, '095 Patent, '120 Patent, and '622 Patent.[211]

531. On June 11, 2021, Biocon filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

532. On September 8, 2021—less than four months after the action began—Biocon and Celgene stipulated and consented to an entry of judgment and an injunction prohibiting Biocon from marketing its generic lenalidomide, "unless and to the extent otherwise specifically

[209] *Celgene Corp. v. Hikma Pharmaceuticals USA, Inc.*, No. 2:21-cv-20459, ECF No. 8 (D.N.J. Jan. 13, 2022).

[210] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Hikma.

[211] *Celgene Corp. v. Biocon Pharma Ltd. et al.*, No. 2:21-cv-11261 (D.N.J.).

authorized by Celgene," until the expiration of the patents-in-suit listed above pursuant to a settlement agreement. The terms of the settlement agreement are not publicly available. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.

i. Celgene's Sham Litigation Against Torrent

533. In Spring 2021, Torrent filed ANDA No. 213405 for generic lenalidomide. On May 10, 2021, Torrent sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Torrent's ANDA.

534. On June 23, 2021, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Torrent for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '740 Patent, '800 Patent, '217 Patent, '569 Patent, '717 Patent, '498 Patent, '095 Patent, '120 Patent, '621 Patent, and '622 Patent.[212]

535. On August 12, 2021—less than two months after the action began—Torrent and Celgene stipulated and consented to an entry of judgment and an injunction prohibiting Torrent from marketing its generic lenalidomide until the expiration of the patents-in-suit listed above pursuant to a settlement agreement. The terms of the settlement agreement are not publicly available and Torrent officials have declined to disclose launch timelines. Plaintiff believes that, given the above anticompetitive reverse payment agreement and complementary agreements discernible with the little public information available, discovery of the settlement agreements

[212] *Celgene Corp. v. Torrent Pharmaceuticals Ltd. et al.*, No. 2:21-cv-12927 (D.N.J.).

will likely reveal anticompetitive provisions that have shielded Celgene's patents from judicial scrutiny and delayed and forestalled price competition in the lenalidomide market.[213]

j. Celgene's Sham Litigation Against Alembic

536. In Fall 2021, Alembic filed ANDA No. 215759 for generic lenalidomide. On October 7, 2021, Alembic sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Alembic's ANDA.

537. On November 18, 2021, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Alembic for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, and '622 Patent.[214]

538. On December 20, 2021, Alembic filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

539. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

VIII. CELGENE AND BRISTOL-MYERS SQUIBB INTENDED TO AND DID HARM COMPETITION

540. Celgene and Bristol-Myers Squibb's scheme was intended to and did in fact block and delay generic thalidomide and lenalidomide entry into the market, destroy incentives for price competition, disrupt the normal distribution channels, and manipulate the statutory and regulatory mechanisms by which generic competition takes place, and otherwise exclude generic competitors from competitively marketing and distributing their products.

[213] As with the Dr. Reddy's settlement, it is likely that Bristol-Myers Squibb approved Celgene's settlement with Torrent.

[214] *Celgene Corp. v. Alembic Pharmaceuticals Ltd. et al.*, No. 2:21-cv-20099 (D.N.J.).

541. But for Celgene and Bristol-Myers Squibb's anticompetitive scheme, generic Thalomid would have been brought to market possibly at least as early as spring 2009. Celgene illegally prevented competitors, including Mylan in 2004, Barr in 2005, and Lannett in 2007, from obtaining Thalomid samples for bioequivalence testing. When Barr filed an ANDA in September 2005, Celgene executed a contract with Barr's API supplier that contained an anticompetitive exclusive dealing provision that created deficiencies in Barr's ANDA application and required Barr to undergo new bio-studies and validation testing, delaying Barr's ANDA one year. When Barr filed its ANDA in September 2006, Celgene filed a sham litigation suit to enforce its invalid and unenforceable patents. The litigation was halted when Celgene and Barr reached a confidential settlement which resulted in a continued absence of generic Thalomid from the market.

542. But for Celgene's anticompetitive conduct, generic Revlimid would have entered the market in 2010 or soon thereafter. Celgene once again prevented multiple competitors including Mylan, Natco Pharma, Dr. Reddy's, Teva, and Watson from obtaining Revlimid from Celgene for BE testing. Celgene refused to supply samples to Mylan, and Mylan has been unable to complete BE testing or file an ANDA for lenalidomide. Natco filed its lenalidomide ANDA in September 2010 and would have brought generic Revlimid to market shortly thereafter, but for Celgene's sham patent infringement lawsuit and the subsequent settlement wherein Natco agreed not to sell generic lenalidomide until 2022, in limited quantities. Dr. Reddy's filed its lenalidomide ANDA in 2016, after which Celgene once again filed a sham patent litigation. Lannett filed its thalidomide ANDA in December 2014, after which Celgene filed a sham patent litigation that resulted in a settlement wherein Lannett's thalidomide could not be sold until August 2019. Zydus, Cipla, Lotus, Hetero, Apotex, Sun, Mylan, Lupin,

Aurobindo, Hikma, Torrent, Biocon, and Alembic each filed lenalidomide ANDAs and were met with Celgene's serial sham litigation tactic, delaying the entry of their generic Revlimid products into the market.

543. All of Celgene's patents on Revlimid are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or doctrines of double-patenting.

544. Celgene's unjustifiable refusal to cooperate with the generic ANDA filers directly prevented generic filers from obtaining FDA approval. But for Celgene's unlawful conduct, FDA would have given final approval to the pending generic manufacturers' ANDAs and allowed them to enter the market as genuine competitors.

545. Celgene cannot justify its scheme by pointing to any consumer benefit. Generic drugs offer enormous cost savings, which outweigh any non-pretextual, if there even are any, justifications Celgene could possibly offer.

IX. CELGENE AND BRISTOL-MYERS SQUIBB'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID CAUSED PLAINTIFF TO PAY MORE THAN IT WOULD HAVE PAID IN AN UNMANIPULATED MARKET

546. Celgene and Bristol-Myers Squibb's scheme suppressed the ability of generic Revlimid and Thalomid substitutes to compete in the market under the governing statutory and regulatory scheme.

547. The absence of generic competition injured Plaintiff because it would have paid less for Thalomid and Revlimid, or their generic alternatives, by substituting purchases of less expensive AB-rated generic drugs for their purchases of more expensive branded drugs, receiving discounts on their remaining purchases of branded drugs, and by purchasing generic versions of Revlimid and Thalomid at lower prices sooner.

548. As a result, Plaintiff has sustained substantial losses and damages to its business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

X. CELGENE AND BRISTOL-MYERS SQUIBB'S FORECLOSURE OF GENERIC COMPETITION FOR REVLIMID AND THALOMID AFFECTED INTERSTATE COMMERCE FOR THOSE DRUGS

549. At all material times, Thalomid and Revlimid, manufactured and sold by Celgene, were shipped across state lines and sold to customers located outside of its state of manufacture.

550. Between at least 2010 and the present, in connection with the purchase and sale of Thalomid and Revlimid, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

551. At all material times, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Celgene and Bristol-Myers Squibb as charged were within the flow of, and have substantially affected interstate commerce, money, contracts, and bills, and other forms of business communications were transmitted in a continuous and uninterrupted flow across state lines.

XI. CELGENE AND BRISTOL-MYERS SQUIBB MAINTAINED MONOPOLY MARKET POWER OVER REVLIMID AND THALOMID AND THEIR GENERIC FORMS

552. At all relevant times, Celgene has had monopoly power over the market for Revlimid and Thalomid in all their forms and dosages, which are still only available in the form of branded Thalomid and branded Revlimid. Celgene has and continues to have the power to maintain and increase the price of Revlimid and Thalomid to supracompetitive levels without

losing sales, because Celgene and Bristol-Myers Squibb have successfully conspired to keep AB-rated generic versions of Revlimid and Thalomid from reaching the U.S. market.

553. A small, but significant, non-transitory price increase for Revlimid or Thalomid by Celgene would not have caused a significant loss of sales.

554. Celgene needed to control only Revlimid and Thalomid and their AB-rated generic equivalents, and no other products, to maintain the price of Revlimid and Thalomid at supracompetitive prices. Only the market entry of a competing AB-rated generic version of those drugs would render Celgene unable to maintain its market monopoly.

555. If Plaintiff is legally required to prove market power through circumstantial evidence by first defining a relevant product market, the relevant market for Thalomid is all dosages of thalidomide, *i.e.*, Thalomid and its AB-rated generic equivalents, and for Revlimid is all dosages of lenalidomide, *i.e.*, Revlimid and its AB-rated generic equivalents.

556. Revlimid and Thalomid do not exhibit significant, positive cross-elasticity of demand regarding price with any other product, due to FDA regulatory hurdles incident to securing an A-B rating and laws allowing pharmacists to substitute only AB-rated generics for prescribed branded drugs.

557. There are no interchangeable drug products available for purchasers of Thalomid and Revlimid.

558. Celgene needed to control the output of Revlimid and Thalomid and its AB-rated generic equivalents only, and no other products, to maintain the price of Revlimid and Thalomid profitably at supracompetitive prices. Only the market entry of a competing AB-rated generic version of Revlimid or Thalomid would render Celgene unable to profitably maintain its current prices of those drugs without losing substantial sales.

559. Celgene also sold branded Revlimid and Thalomid well over marginal costs, and substantially more than the competitive price, and enjoyed unusually high profit margins.

560. Celgene has had, and so exercised, the power to exclude and restrict competition for Thalomid and Revlimid.

561. Without the power to exclude and restrict competition for Thalomid and Revlimid, and the ability to sell its own branded version of those drugs at prices well over marginal costs, it would not have been economically rational for Celgene to make exorbitant payments to settle with Natco to delay the launch of generic Thalomid and Revlimid.

562. At all relevant times, Celgene has enjoyed the benefits of high barriers to entry with respect to competition to the above-defined market due to patent and other regulatory protections.

563. The relevant geographic markets are (i) the United States and its territories, and (ii) each state in which Plaintiff purchased Revlimid and/or Thalomid and under whose laws Plaintiff assert claims for relief. Celgene's market share in the relevant market was 100% until March 2022, is 100% of the non-volume limited segment of the market for lenalidomide, and remains at least 90% of the overall market for lenalidomide.

XII. ANTITRUST INJURY

564. Celgene and Bristol-Myers Squibb's use of the regulatory process as an anticompetitive tool to block and delay generic competition for Revlimid and Thalomid keeps costs high for insurers like Plaintiff.

565. Plaintiff paid substantial sums to purchase Revlimid and Thalomid during the relevant times and their members paid additional sums in cost-sharing for Thalomid and Revlimid. Because of Celgene's illegal conduct, Plaintiff has been compelled to pay artificially inflated prices for Thalomid and Revlimid. Those prices have been substantially higher than the

prices Plaintiff would have paid for generic Thalomid and generic Revlimid but for the illegal conduct alleged. Plaintiff continues to pay artificially high, supracompetitive prices for Revlimid and Thalomid as a direct and proximate result of Celgene's anticompetitive conduct.

566. Consequently, Plaintiff, a purchaser of Thalomid and Revlimid, having paid for Thalomid and Revlimid, has sustained substantial losses and damage to its business and property in the form of overcharges. The full amount, forms, and components of such damages will be determined after discovery and upon proof at trial.

567. Celgene's efforts to restrain competition in the defined relevant markets has and continues to substantially affect interstate and intrastate commerce throughout the United States.

568. Excluding generic competitors and capping their volume of sales at a small fraction of the market prevented price competition for Thalomid and Revlimid.

569. Prices for Revlimid and Thalomid have been and will continue to be inflated as a direct and foreseeable result of Celgene's anticompetitive conduct. The inflated prices that Plaintiff has paid and will continue to pay are traceable to, and are the proximate foreseeable result of, the overcharges by Celgene.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade Under State Law

570. Plaintiff incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

571. Defendants entered into an agreement or combination in restraint of trade in violation of many states' laws. Defendants and Natco engaged in a continuing contract, combination or conspiracy with respect to the sale of Revlimid in unreasonable restraint of trade and commerce, in violation of the various state antitrust statutes set forth below.

572. Defendants and Natco entered into an unlawful reverse payment agreement that restrained, and continues to restrain, competition in the market for Revlimid and/or its AB-rated generic equivalents.

573. Defendants and Natco's acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for Revlimid and/or its AB-rated generic equivalents.

574. As a result of Defendants and Natco's unlawful conduct, Plaintiff has been harmed by being forced to pay artificially inflated, supracompetitive prices for Revlimid.

575. In formulating and carrying out the alleged agreement, understanding, contract, combination, and conspiracy, Defendants and Natco did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

576. Defendants and Natco's conspiracy had the following effects, among others: the reverse payment agreement between Defendants and Natco delayed generic entry and its attendant lower prices for Plaintiff, and the market allocation output restriction agreement effectively fixed prices at an artificially high level.

577. Brand Defendant and Natco engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, raise, maintain, or stabilize prices of Revlimid.

578. There was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on Plaintiff and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary

to achieve the purpose. Accordingly, these acts constitute violations of the antitrust laws of various states in accordance with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

579. By engaging the foregoing conduct, Defendants and Natco intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona.

b) C.G.S.A. §§ 35-26 and 28, et seq., with respect to purchases in Connecticut.

c) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia.

d) Haw. Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii.

e) 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchases in Illinois.

g) Iowa Code § 553.1, et seq., with respect to purchases in Iowa.

g) Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas.

h) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine.

i) MD Code Ann., Com. Law, §§ 11-204, et seq., with respect to purchases in Maryland.

j) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan.

k) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. §§ 8.31, et seq., with respect to purchases in Minnesota.

l) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi.

m) Neb. Rev. Stat. Ann. §§ 59-801, et seq., with respect to purchases in Nebraska.

n) Nev. Rev. Stat. Ann. §§ 598A.010, et seq., with respect to purchases in Nevada.

o) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire.

p) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico.

q) N.Y. Gen. Bus. Law § 340, et seq., with respect to purchases in New York.

r) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina.

s) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota.

t) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon.

u) P.R. Laws Ann. tit. 10 §§ 258, et seq., with respect to purchases in Puerto Rico.

v) R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases in Rhode.

w) S.D. Codified Laws §§ 37-1-3.1, et seq., with respect to purchases in South Dakota.

x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee.

y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah.

z) W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia.

aa) Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin.

580. Plaintiff has been injured in its business or property by reason of Defendants' violations of the laws set forth above, in that they were, and continue to be: (i) denied the opportunity to purchase lower-priced generic Revlimid; and (ii) paid higher prices for Revlimid than they would have paid but for Defendants' unlawful conduct. These injuries are of the type that the above laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

581. Plaintiff seeks damages and multiple damages as permitted by law.

SECOND CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law

582. Plaintiff incorporates by reference the preceding allegations.

583. Celgene possessed monopoly power in the defined relevant market at all times since its NDAs for Revlimid and Thalomid were respectively approved. Celgene knowingly and willfully engaged in a course of exclusionary conduct designed to prevent generic manufacturers from entering the market and unlawfully extended its monopoly power.

584. Celgene intentionally extended its monopoly power in the relevant market through its anticompetitive and illegal scheme. Thus, Plaintiff paid artificially inflated prices for its indirect purchases of Thalomid and Revlimid, including by assignment from its subsidiaries. There is and was no non-pretextual justification for Celgene's anticompetitive actions.

585. As a direct and proximate result of Celgene's conduct, as alleged herein, Plaintiff was injured.

586. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases of Revlimid and Thalomid in Arizona.
b. D.C. Code §§ 28-4503, et seq., with respect to purchases of Revlimid and Thalomid in the District of Columbia.
c. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Revlimid and Thalomid in Florida.
d. Hawaii Code §§ 480, et seq., with respect to purchases of Revlimid and Thalomid in Hawaii.
e. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Revlimid and Thalomid in Illinois.
f. Iowa Code §§ 553.5 et seq., with respect to purchases of Revlimid and Thalomid in Iowa.
g. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases of Revlimid and Thalomid in Massachusetts by Plaintiff, who paid substantially higher prices for Revlimid and Thalomid in actions and transactions occurring substantially within Massachusetts.
h. Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases of Revlimid and Thalomid in Maine.
i. Mich. Comp. Laws Ann. §§ 445.773, et seq., with respect to purchases of Revlimid and Thalomid in Michigan.
j. Minn. Stat. §§ 325D.52, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Revlimid and Thalomid in Minnesota.
k. Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases of Revlimid and Thalomid in Mississippi.
l. Neb. Code Ann. §§ 59-802, et seq., with respect to purchases of Revlimid and Thalomid in Nebraska.
m. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Revlimid and Thalomid in Nevada by Plaintiff, who paid substantially higher prices for Revlimid and Thalomid in actions and transactions occurring substantially within Nevada.
n. N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to purchases of Revlimid and Thalomid in New Hampshire.
o. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases of Revlimid and Thalomid in New Mexico.
p. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases of Revlimid and Thalomid in North Carolina.
q. N.D. Cent. Code §§ 51-08.1-03, et seq., with respect to purchases of Revlimid and Thalomid in North Dakota.
r. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases of Revlimid and Thalomid in Oregon.
s. 10 L.P.R.A. §§ 257, et seq., with respect to purchases of Revlimid and Thalomid in Puerto Rico.

t. R.I. Gen. Laws §§ 6-36-1, et seq., with respect to purchases of Revlimid and Thalomid in Rhode Island.
u. S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to purchases of Revlimid and Thalomid in South Dakota.
v. Utah Code Ann. §§ 76-10-911, et seq., with respect to purchases of Revlimid and Thalomid in Utah.
w. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases of Revlimid and Thalomid in Vermont.
x. W.Va. Code §§ 47-18-4, et seq., with respect to purchases of Revlimid and Thalomid in West Virginia.
y. Wis. Stat. §§ 133.03, et seq., with respect to purchases of Revlimid and Thalomid in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiff paid substantially higher prices for Revlimid and Thalomid at Wisconsin pharmacies.

THIRD CLAIM FOR RELIEF
Attempted Monopolization Under State Law

587. Plaintiff incorporates by reference the preceding allegations.

588. Celgene, through its anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Celgene's conscious objective to control prices and exclude competition in the relevant market.

589. The natural, intended, and foreseeable consequences of Celgene's anticompetitive scheme was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

590. There is a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Celgene will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

591. As a direct and proximate result of Celgene's conduct, Plaintiff was harmed with respect to its indirect purchases of Revlimid and Thalomid as aforesaid.

592. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, et seq., with respect to purchases of Revlimid and Thalomid in Arizona.
b. Conn. Gen. Stat. §§ 35-27, et seq., with respect to purchases of Revlimid and Thalomid in Connecticut.
c. D.C. Code §§ 28-4503, et seq., with respect to purchases of Revlimid and Thalomid in the District of Columbia.
d. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Revlimid and Thalomid in Florida.
e. Hawaii Code §§ 480, et seq., with respect to purchases of Revlimid and Thalomid in Hawaii.
f. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases of Revlimid and Thalomid in Illinois.
g. Iowa Code §§ 553.5 et seq., with respect to purchases of Revlimid and Thalomid in Iowa.
h. Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases of Revlimid and Thalomid in Maine.
i. Md. Code, Com. Law §§ 11-204, et seq., with respect to purchases of Revlimid and Thalomid in Maryland.
j. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases of Revlimid and Thalomid in Massachusetts by Plaintiff, who paid substantially higher prices for Revlimid and Thalomid in actions and transactions occurring substantially within Massachusetts.
k. Mich. Comp. Laws Ann. §§ 445.773, et seq., with respect to purchases of Revlimid and Thalomid in Michigan.
l. Minn. Stat. §§ 325D.52, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases of Revlimid and Thalomid in Minnesota.
m. Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases of Revlimid and Thalomid in Mississippi.
n. Neb. Code Ann. §§ 59-802, et seq., with respect to purchases of Revlimid and Thalomid in Nebraska.
o. Nev. Rev. Stat. Ann. §§ 598A.060, et seq., with respect to purchases of Revlimid and Thalomid in Nevada by Plaintiff, who paid substantially higher prices for Revlimid and Thalomid in actions and transactions occurring substantially within Nevada.
p. N.H. Rev. Stat. Ann. §§ 356.1, et seq., with respect to purchases of Revlimid and Thalomid in New Hampshire.
q. N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases of Revlimid and Thalomid in New Mexico.
r. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases of Revlimid and Thalomid in New York.
s. N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases of Revlimid and Thalomid in North Carolina.
t. N.D. Cent. Code §§ 51-08.1-03, et seq., with respect to purchases of Revlimid and Thalomid in North Dakota.
u. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases of Revlimid and Thalomid in Oregon.

v. 10 L.P.R.A. §§ 257, et seq., with respect to purchases of Revlimid and Thalomid in Puerto Rico.
w. R.I. Gen. Laws §§ 6-36-1 et seq., with respect to purchases of Revlimid and Thalomid in Rhode Island.
x. S.D. Codified Laws §§ 37-1-3.2, et seq., with respect to purchases of Revlimid and Thalomid in South Dakota.
y. Utah Code Ann. §§ 76-10-911, et seq., with respect to purchases of Revlimid and Thalomid in Utah.
z. Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases of Revlimid and Thalomid in Vermont.
aa. W.Va. Code §§ 47-18-4, et seq., with respect to purchases of Revlimid and Thalomid in West Virginia.
bb. Wis. Stat. §§ 133.03, et seq., with respect to purchases of Revlimid and Thalomid in Wisconsin by Plaintiff, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Plaintiff paid substantially higher prices for Revlimid and Thalomid at Wisconsin pharmacies.

FOURTH CLAIM FOR RELIEF
Unfair and Deceptive Trade Practices Under State Law

593. Plaintiff incorporates by reference the preceding allegations.

594. Celgene engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Celgene's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff was deprived of the opportunity to purchase generic versions of Revlimid and Thalomid and forced to pay artificially inflated prices for these drugs.

595. There was and is a gross disparity between the price that Plaintiff paid and continue to pay for its indirect purchases of Thalomid and Revlimid, including by assignment from their subsidiaries, and the value received, given that a much cheaper substitute generic product should be available, and prices for Revlimid and Thalomid should be much lower, but for Celgene's unlawful scheme.

596. By engaging in the foregoing conduct, Celgene has engaged in in unfair competition or deceptive acts and practices in violation of the following state laws:

a. Ark. Code §§ 4-88-101, et seq., with respect to purchases of Revlimid and Thalomid in Arkansas.
b. Ariz. Code §§ 44-1522, et seq., with respect to purchases of Revlimid and Thalomid in Arizona.
c. Colo. Rev. Stat § 6-1-105, et seq., with respect to purchases of Revlimid and Thalomid in Colorado.
d. Conn. Gen. Stat. §§ 35-27, et seq., with respect to purchases of Revlimid and Thalomid in Connecticut.
e. D.C. Code §§ 28-3901, et seq., with respect to the purchases of Revlimid and Thalomid in the District of Columbia.
f. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Revlimid and Thalomid in Florida.
g. Idaho Code §§ 48-601, et seq., with respect to the purchases of Revlimid and Thalomid in Idaho.
h. 815 ILCS §§ 505/1, et seq., with respect to the purchases of Revlimid and Thalomid in Illinois.
i. Ind. Code §§ 24-5-0.5-1, et seq., with respect to the purchases of Revlimid and Thalomid in Indiana.
j. Kan. Stat. §§ 50-623, et seq., with respect to the purchases of Revlimid and Thalomid in Kansas.
k. La. Rev. Stat. Ann. § 51:1401, et seq., with respect to the purchases of Revlimid and Thalomid in Louisiana.
l. 5 Me. Rev. Stat. §§ 207, et seq., with respect to the purchases of Revlimid and Thalomid in Maine.
m. Md. Code, Com. Law §§ 11-204, et seq., with respect to purchases of Revlimid and Thalomid in Maryland.
n. Mass. Ann. Laws ch. 93A, et seq., with respect to purchases of Revlimid and Thalomid in Massachusetts.
o. Mich. Stat. §§ 445.901, et seq., with respect to purchases of Revlimid and Thalomid in Michigan.
p. Minn. Stat. § 325D.43, et. seq., Minn. Stat. §§ 325F.69, *et seq*., and Minn. Stat. §§ 8.31, et seq., with respect to purchases of Revlimid and Thalomid in Minnesota.
q. Miss. Code. Ann. §§ 75-24-1, et seq., with respect to purchases of Revlimid and Thalomid in Mississippi.
r. Missouri Stat. §§ 407.010, et seq., with respect to purchases of Revlimid and Thalomid in Missouri.
s. Neb. Rev. Stat. §§ 59-1601, et seq., with respect to purchases of Revlimid and Thalomid in Nebraska.
t. Nev. Rev. Stat. §§ 598.0903, et seq., with respect to purchases of Revlimid and Thalomid in Nevada.
u. N.H. Rev. Stat. §§ 358-A:1, et seq., with respect to purchases of Revlimid and Thalomid in New Hampshire.
v. N.M. Stat. §§ 57-12-1, et seq., with respect to purchases of Revlimid and Thalomid in New Mexico.

w. N.Y. Gen. Bus. Law §§ 349, et seq., with respect to purchases of Revlimid and Thalomid in New York.
x. N.C. Gen. Stat. §§ 75-1.1, et seq., with respect to purchases of Revlimid and Thalomid in North Carolina.
y. N.D. Cent. Code §§ 51-15-01, et seq., with respect to purchases of Revlimid and Thalomid in North Dakota.
z. Or. Rev. Stat. §§ 646.605, et seq., with respect to purchases of Revlimid and Thalomid in Oregon.
aa. 73 Pa. Stat. Ann. §§ 201-1, et seq., with respect to purchases of Revlimid and Thalomid in Pennsylvania.
bb. S.C. Stat. Ann. §§ 39-5-10, et seq., for purchases of Revlimid and Thalomid in South Carolina.
cc. S.D. Code Laws §§ 37-24-1, et seq., with respect to purchases of Revlimid and Thalomid in South Dakota.
dd. Utah Code §§ 13-11-1, et seq., with respect to purchases of Revlimid and Thalomid in Utah.
ee. 9 Vt. §§ 2451, et seq., with respect to purchases of Revlimid and Thalomid in Vermont.
ff. Va. Code Ann. §§ 59.1-196, et seq., with respect to purchases of Revlimid and Thalomid in Virginia.
gg. W.Va. Code §§ 46A-6-101, et seq., with respect to purchases of Revlimid and Thalomid in West Virginia.
hh. Wis. Stat. § 100.18; Wis. Stat. § 100.20, et. seq., with respect to purchases of Revlimid and Thalomid in Wisconsin.
ii. Wyo. Stat. Ann. §§ 40-12-101, et seq., with respect to purchases of Revlimid and Thalomid in Wyoming.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law

597. Plaintiff incorporates by reference the preceding allegations.

598. Celgene has benefitted from monopoly profits on the sale of Revlimid and Thalomid resulting from the unlawful and inequitable acts alleged in this Complaint.

599. Celgene's financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for indirect purchases of Revlimid and Thalomid by Plaintiff.

600. Plaintiff has conferred upon Celgene an economic benefit, profits from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff.

601. It would be futile for Plaintiff to seek a remedy from any party with whom they have privity of contract for its indirect purchases of Thalomid and Revlimid.

602. It would be futile for Plaintiff to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Thalomid and Revlimid, as they are not liable and would not compensate Plaintiff for unlawful conduct caused by Celgene.

603. The economic benefit of overcharges and monopoly profits derived by Celgene through charging supracompetitive and artificially inflated prices for Revlimid and Thalomid is a direct and proximate result of Celgene's unlawful conduct.

604. The economic benefits derived by Celgene rightfully belong to Plaintiff, as it paid anticompetitive and monopolistic prices for Revlimid and Thalomid beginning in at least 2010 and continuing through the present, and it will continue to do so until the effects of Celgene's illegal and anticompetitive conduct cease.

605. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Celgene to be permitted to retain any of the overcharges for Revlimid and Thalomid derived from Celgene's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

606. Celgene is aware of and appreciates the benefits bestowed upon it by Plaintiff.

607. Celgene should be compelled to disgorge in a common fund for the benefit of Plaintiff all unlawful or inequitable proceeds it received.

608. A constructive trust should be imposed upon all unlawful or inequitable sums received by Celgene traceable to Plaintiff.

SIXTH CLAIM FOR RELIEF

Injunctive Relief under Section 16 of the Clayton Act for Violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2

609. Plaintiff incorporates by reference the preceding allegations.

610. Plaintiff seeks equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by Celgene's unlawful conduct, and to assure that similar anticompetitive conduct and effects do not continue or reoccur in the future.

XIV. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff demands judgment against Celgene, as follows:

611. Awarding Plaintiff actual, consequential, compensatory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post- judgment interest at the statutory rates;

612. Awarding Plaintiff equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Celgene's unjust enrichment.

613. Declaring the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

614. Awarding Plaintiff its reasonable costs and expenses, including attorneys' fees; and

615. Awarding all other legal or equitable relief as the Court deems just and proper.

XV. JURY DEMAND

Plaintiff demands a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38(b).

Dated: July 13, 2022

Respectfully submitted:

LOWEY DANNENBERG, P.C.

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